USER: **PROPHET WRIGHT, ANGELA R (arp)**

FOLDER: **K980558 - 162 pages (FOI:08006272)**

COMPANY: **I-FLOW CORP. (IFLOW)**

PRODUCT: **PUMP, INFUSION, ELASTOMERIC (MEB)**

SUMMARY: **Product: PAINBUSTER INFUSION SYSTEM**

DATE REQUESTED: **Fri Nov 07 24:00:00 2008**

DATE PRINTED: **Thu Nov 13 11:59:23 2008**

Note: **Releasable Version**

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I-FLOW
CORPORATION

20202 Windrow Drive
Lake Forest, CA 92630
(800) 448-3569 (714) 206-2700
Fax (714) 206-2600

K980558

MAY 28 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

February 11, 1998

Trade Name: PainBuster

Common Name: Elastomeric Infusion Pump

Classification Name: Pump, Infusion, Elastomeric

All questions and/or comments concerning this document should be made to:

Robert J. Bard, Esq., R.A.C.
Vice President Regulatory and Legal Affairs

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Telephone: 714.206.2700
Fax: 714.206.2600

1.0 GENERAL INFORMATION

1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to market an intraoperative site infusion kit, the PainBuster™ Infusion System, that utilizes legally marketed components for a new intended use.

1.2 Statement of Equivalence

1.2.1 The PainBuster Infusion System is a kit which includes components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation).

1.2.2 The PainBuster Infusion System is substantially equivalent in intended use to the Pain Control Infusion Pump (PCIP) (K896422) distributed by Sgarlato Laboratories, Inc.

1.2.2.1 The Sgarlato PCIP kit contains an infusion pump produced by Burron/B. Braun, B. Braun catheter and Jelco needle.

1.2.2.2 The catheter and needle included in the PainBuster kit are separately purchased pre-amendment or 510(k) devices similar to the devices in the Sgarlato PCIP kit.

1.2.2.2.1 An example of the catheter included in the PainBuster kit is the B. Braun Perifix® Epidural Catheter Set.

1.2.2.2.2 An example of the needle included in the PainBuster kit is the Jelco™ Catheter Introducer Needle.

1.2.2.2.3 The PainBuster pump is substantially equivalent to the Homepump C-Series (K944692) and Homepump Eclipse (K932740) marketed by I-Flow Corporation.

1.2.2.3 The PainBuster pump's design is nearly identical to the original Homepump C-Series, see section 2.1 below.

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of Device

2.1.1 The PainBuster Infusion System is a kit that is comprised of an elastomeric infusion pump, a catheter and a needle.

2.1.2 The PainBuster pump is the Homepump C-Series with a new intended use. The pump design is identical to the original Homepump C-Series except as follows:

2.1.2.1 The PainBuster pump utilizes the same soft PVC shell that the Homepump Eclipse uses.

2.1.2.2 The two (2) outer natural latex bladders have been replaced by a single thicker natural latex bladder.

2.1.2.3 The PainBuster pump is intended to be used with a catheter that is included with the kit.

2.2 Product Configuration

2.2.1 Models

2.2.1.1 P065005: 65 ml volume, 0.5 ml/hr flow rate

2.2.1.2 P125015: 125 ml volume, 1.5 ml/hr flow rate

2.2.1.3 P125020: 125 ml volume, 2.0 ml/hr flow rate

2.2.2 Each model consists of a kit with the following components:

2.2.2.1 (1) PainBuster pump.

2.2.2.2 (1) Catheter

2.2.2.2.1 20 G catheter, 11 to 40 in. length, polyamide or nylon or FEP (fluorinated ethylene propylene) polymer.

2.2.2.2.2 A catheter connector is included to connect the catheter to the distal luer of the administration set.

2.2.2.2.3 The B. Braun Perifix® Epidural Catheter Set is an example of the type of catheter that may be used with the PainBuster Infusion System.

2.2.2.2.3.1 Product code: EC20-0

2.2.2.2.3.2 510(k) number: K813186

2.2.2.3 (1) Needle:

2.2.2.3.1 14 to 18G, 1 ½ to 2 ¼ in. length, stainless steel.

2.2.2.3.2 The needle may be a catheter over needle as in the Jelco™ example below.

2.2.2.3.3 The Jelco™ Catheter Introducer Needle is an example of the type of catheter introducer needle that may be used with the PainBuster Infusion System.

2.2.2.3.3.1 Product code: 4058

2.2.2.4 (1) Directions for Use (DFU)

2.3 Components and Materials

All the components used in the PainBuster pump are identical to those used in the Homepump Eclipse or Homepump C-Series.

The PainBuster Infusion System is a disposable device intended for single use.

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 Standard Operating Conditions:

Priming Volume:	less than 5.0 ml
Residual Volume:	less than 5.0 ml
Operating Temperature	31°C (skin temperature)
Test Solution:	0.9% NaCl
Operating Pressure:	9 to 14 psi
Head Height:	16"
Accuracy:	±15% at 95% confidence interval

3.2 **Flow Rate Performance Data**: Testing occurred at 31°C and at the nominal head height of 16".

	65ml x 0.5ml/hr	125ml x 2.0ml/hr
Average Flow Rate	0.48 ml/hr	1.98 ml/hr
Std. Dev.	0.02	0.05
n	27	26

65ml x 0.5ml/hr: A twenty seven (27) piece sample produced an average flow rate of 0.48 ml/hr. The resulting average is well within it's ±15% accuracy claim. The fastest infusion had an average flow rate of 0.53 ml/hr and the slowest infusion had an average flow rate of 0.41 ml/hr.

125ml x 2.0ml/hr: A twenty six (26) piece sample produced an average flow rate of 1.98 ml/hr. The resulting average is well within it's ±15% accuracy claim. The fastest infusion had an average flow rate of 2.05 ml/hr and the slowest infusion had an average flow rate of 1.83 ml/hr.

3.3 **Back Pressure Comparison:** Testing was performed on the Homepump Eclipse 65ml x 0.5ml/hr and 100ml x 2.0ml/hr to determine the effects of back pressure on the flow rate. Testing occurred at the nominal head height of 16", at a head height of 42" and at 3.1 psi. Ten samples at each back pressure were tested. The test results for flow rate at each pressure for each product are summarized in the following table.

	65ml x 0.5ml/hr			100ml x 2.0ml/hr		
Test Pressure	16" HH	42" HH	3.1 psi	16" HH	42" HH	3.1 psi
Average Flow Rate (ml/hr)	0.51	0.49	0.45	1.96	1.77	1.79
Std. Dev.	0.03	0.02	0.03	0.09	0.08	0.08
n	15	10	10	15	15	15

The average decrease in flow rates produced by the increased back pressure is as expected.

3.4 **Drug Delivery Comparison:** The Homepump Eclipse 65ml x 0.5ml/hr has been tested to assess how a 5% Dextrose solution affects flow rate. The performance of the system is affected by the viscosity or density of a solution. The flow rate was measured at 31°C. The resulting data is presented below.

Note: Local anesthetics have densities similar to normal saline (e.g. 1.0035 for Bupivacaine).

	65ml x 0.5ml/hr	
	Saline	5% Dextrose
Average Flow Rate (ml/hr)	0.49	0.46
Std.Dev.	0.02	0.02
n	30	15

65ml x 0.5ml/hr: The 5% Dextrose solution flow rate was 6% slower than the normal saline solution.

Product labeling includes a statement as to delivery times and the possible deviation from nominal.

3.5 **Catheters and PICC Lines:** The Homepump Eclipse 65ml x 0.5ml/hr has been tested to assess how a 20 G x 60 cm PICC line and 23 G x 28 cm epidural catheter affects flow rate. The tests were performed at room temperature and 31°C at the nominal head height of 16". The results are summarized in the table below.

		Average (ml/hr)	Std Dev.	Maximum (ml/hr)	Minimum (ml/hr)
PICC Line	Room Temp.	0.41	0.02	0.44	0.39
	31°C	0.51	0.03	0.58	0.48
Epidural Catheter	Room Temp.	0.38	0.04	0.45	0.32
	31°C	0.53	0.02	0.56	0.49

The PICC line and epidural catheter had no effect on flow.

4.0 BIOLOGICAL SPECIFICATIONS

4.1 Biological testing is in conformance with ISO 10993 Part 1 for all fluid path components.

5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Compatibility

5.1.1 There are no specific drugs referenced in the labeling for the PainBuster Infusion System.

5.1.2 The PainBuster Infusion System is intended for use with general local anesthetics.

6.0 INTENDED USE

6.1 The PainBuster is intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

6.2 The PainBuster is intended to deliver pain medication percutaneously via an administration set attached to a catheter.

6.3 The PainBuster is not intended for epidural, subcutaneous or vascular drug delivery.

6.4 The PainBuster is single use only.

6.5 No testing has been conducted to determine the efficacy of the PainBuster for the delivery of blood, blood products or TPN. The PainBuster is not intended for the delivery of blood, blood products or TPN.

6.6 The PainBuster is suitable for use as an ambulatory device and is intended for use in the home environment but not limited to use in the home environment.

7.0 PACKAGING

7.1 The PainBuster kit components are packaged individually in either sterile Tyvek® pouches or sterile Form/Fill/Seal trays. The components of the kit are packaged in a sealed tray.

7.1.1 Packaging is suitable for either radiation or ETO sterilization.

8.0 STERILIZATION INFORMATION

Note: The catheter and needle components of the PainBuster Infusion System may be purchased non-sterile and packaged by I-Flow or sterile from the manufacture. The PainBuster pump and non-sterile purchased components shall be sterilized as follows:

8.1 The methods of sterilization are gamma radiation (Cobalt 60) or ETO gas.

(b)(4)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1998

Robert J. Bard, Esq. R.A.C.
Vice President Regulatory and Legal Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, California 92630

Re: K980558
Trade Name: PainBuster Infusion System
Regulatory Class: II
Product Code: MEB
Dated: April 27, 1998
Received: April 28, 1998

Dear Mr. Bard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

I-FLOW
CORPORATION

20202 Windrow Drive
Lake Forest, CA 92630
(800) 448-3569 (714) 206-2700
Fax (714) 206-2600

510(k) Number (if known): K980558

Device Name: PainBuster™ Infusion System

Indications for Use:

1. The PainBuster is intended to provide continuous infusion of a local anesthetic directly into the intraoperative (soft tissue / body cavity) site for postoperative pain management.
2. The PainBuster is intended to deliver pain medication percutaneously via an administration set attached to a catheter.
3. The PainBuster is single use only.
4. The PainBuster is suitable for use as an ambulatory device and is intended for use in the home environment but not limited to use in the home environment.
5. The PainBuster is not intended for epidural, subcutaneous or vascular drug delivery.
6. The PainBuster is not intended for chemotherapy drugs.
7. No testing has been conducted to determine the efficacy of the PainBuster for the delivery of blood, blood products or TPN. The PainBuster is not intended for the delivery of blood, blood products or TPN.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUED ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Patricia Cascante
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K980558

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1998

Robert J. Bard, Esq. R.A.C.
Vice President Regulatory and Legal Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, California 92630

Re: K980558
Trade Name: PainBuster Infusion System
Regulatory Class: II
Product Code: MEB
Dated: April 27, 1998
Received: April 28, 1998

Dear Mr. Bard:

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Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2

I-FLOW
CORPORATION
Lake Forest, CA 92630
(800) 448-3569 (714) 206-2700
Fax (714) 206-2600

510(k) Number (if known): K980558

Device Name: PainBuster™ Infusion System

Indications for Use:

1. The PainBuster is intended to provide continuous infusion of a local anesthetic directly into the intraoperative (soft tissue / body cavity) site for postoperative pain management.
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUED ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Patricia Cincotta
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K980558

(Optional Format 1-2-96)

B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

om: Reviewer(s) - Name(s) William M. Burdick

Memorandum

Subject: 510(k) Number K980558/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☐ Accepted for review 2/26/98
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? ☐ YES ☐ NO

- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☒ YES	☐ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)?	☐ YES	☒ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices N/A

☒ The indication for use form (required for originals received 1-1-96 and after)

☐ Animal Source Material ☐ Human Tissue Product ☐ Human Cell Product ☐ Human Extraction Product
(Please Check All That Apply)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 80 MEB; Class II 880.5725 Infusion Pump

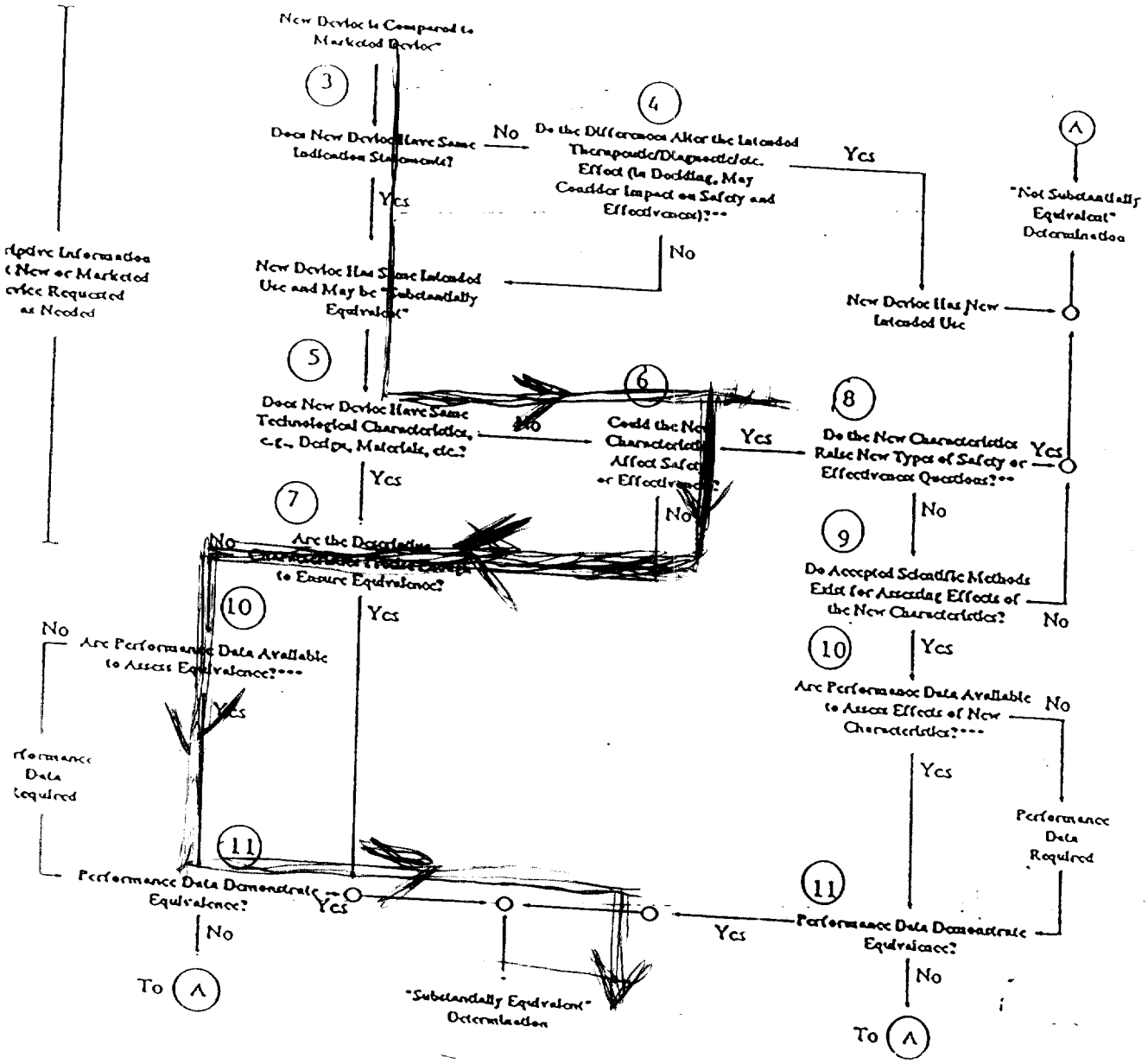
Additional Product Code(s) with panel (optional): 80 FPA; Class II

vie (Branch Chief) (Branch Code) (Date)

al Review: (Division Director) (Date)

ised:2/19/98

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

** It may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K980058

Reviewer: William M. Burdick

Division/Branch: DDIGD/GHDB

Device Name: PainBuster™ Infusion System

Product To Which Compared (510(K) Number If Known): Please refer to 3L of attached "510(k) REVIEW".

	YES	NO	
1. Is Product A Device	X		If **NO** = Stop
2. Is Device Subject To 510(k)?	X		If **NO** = Stop
3. Same Indication Statement?	X		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5. Same Technological Characteristics?		X	If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		X	If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?	X		If **NO** = Request Data
11. Data Demonstrate Equivalence?	X		Final Decision: **SE**

(Continued on Next Page.)

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1. *Intended Use*: Please refer to #2 of attached "510(k) REVIEW".

2. *Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.*

Please refer to #1 of attached "510(k) REVIEW".

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. *Explain why not a device*: N/A

2. *Explain why not subject to 510(k)*: N/A

3. *How does the new indication differ from the predicate device's indication*: N/A

4. *Explain why there is or is not a new effect or safety or effectiveness issue*: N/A

5. *Describe the new technological characteristics*: Please refer to 3N of attached "510(k) REVIEW".

6. *Explain how new characteristics could or could not affect safety or effectiveness*: Since conformance to AAMI/ANSI ID26-1992 was not certified by I-Flow, important testing required to verify the safety and effectiveness of the infusion pump may not have been performed.

7. *Explain how descriptive characteristics are not precise enough*: I-Flow needed to show that the testing they performed was at least as accurate in assessing the safety and effectiveness of their pump as the testing required in AAMI/ANSI ID26-1992.

8. *Explain new types of safety or effectiveness questions raised or why the questions are not new*: N/A

9. *Explain why existing scientific methods can not be used*: N/A

10. *Explain what performance data is needed*: In particular, the flow rate testing results was needed.

11. *Explain how the performance data demonstrates that the device is or is not substantially equivalent*: I-Flow was able to show that the flow rate and other testing they performed were equivalent to AAMI/ANSI ID26-1992.

ATTACH ADDITIONAL SUPPORTING INFORMATION

Please refer to the attached "510(k) REVIEW".

7

MEMO TO THE RECORD

510(K) REVIEW

K980058

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(b)(4)

FOI

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DEPARTMENT OF HEALTH AND HUMAN SERVICES — Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 29, 1998

I-FLOW CORP.
20202 WINDROW DR.
LAKE FOREST, CA 92630
ATTN: ROBERT J. BARD, ESQ., R.A.C.

510(k) Number: K980558
Product: PAINBUSTER INFUSION SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

14

I·FLOW®
-FLOW
CORPORATION
Lake Forest, CA 92630
(800) 448-3569 (714) 206-2700
Fax (714) 206-2600

Via UPS
April 27, 1998

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center HFZ 401
9200 Corporate Blvd.
Rockville, MD 20850

Re: K980558

Reviewing Staff:

As requested by Mr. Bill Burdic, of the ODE Reviewing Staff, I-Flow Corporation is providing the attached additional information for The PainBuster Infusion System (K980558).

The requested information is for the 125 ml volume 1.5 ml/hr PainBuster pump (Ref P125015) for the device's flow profile (including graph, raw data and text information.

Hopefully, this information is sufficient to allow the ODE staff to complete its review of the submission. If additional information is needed for this product, please contact me at:

Phone 949.206.2670 (or 949.206.2700) or Fax 949.206.2603

Sincerely,

Robert J. Bard, Esq.
Vice President Regulatory and Legal Affairs

SK-1

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3.0

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DEPARTMENT OF HEALTH AND HUMAN SERVICES — Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 28, 1998

I-FLOW CORP.
20202 WINDROW DR.
LAKE FOREST, CA 92630
ATTN: ROBERT J. BARD, ESQ., R.A.C.

510(k) Number: K980558
Product: PAINBUSTER
INFUSION SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) William M. Burdick

Subject: 510(k) Number K980538

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☒ Requires additional information (other than refuse to accept). Telephone "HOLD"
- ☐ Accepted for review _____.
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices N/A

☒ The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class and tier: Additional Product Code(s) with panel (optional):

Review: Rebecca Cucerida (Branch Chief) GHQB (Branch Code) 4-27-98 (Date)

Final Review: _____ (Division Director) _____ (Date)

Revised:7/21/97

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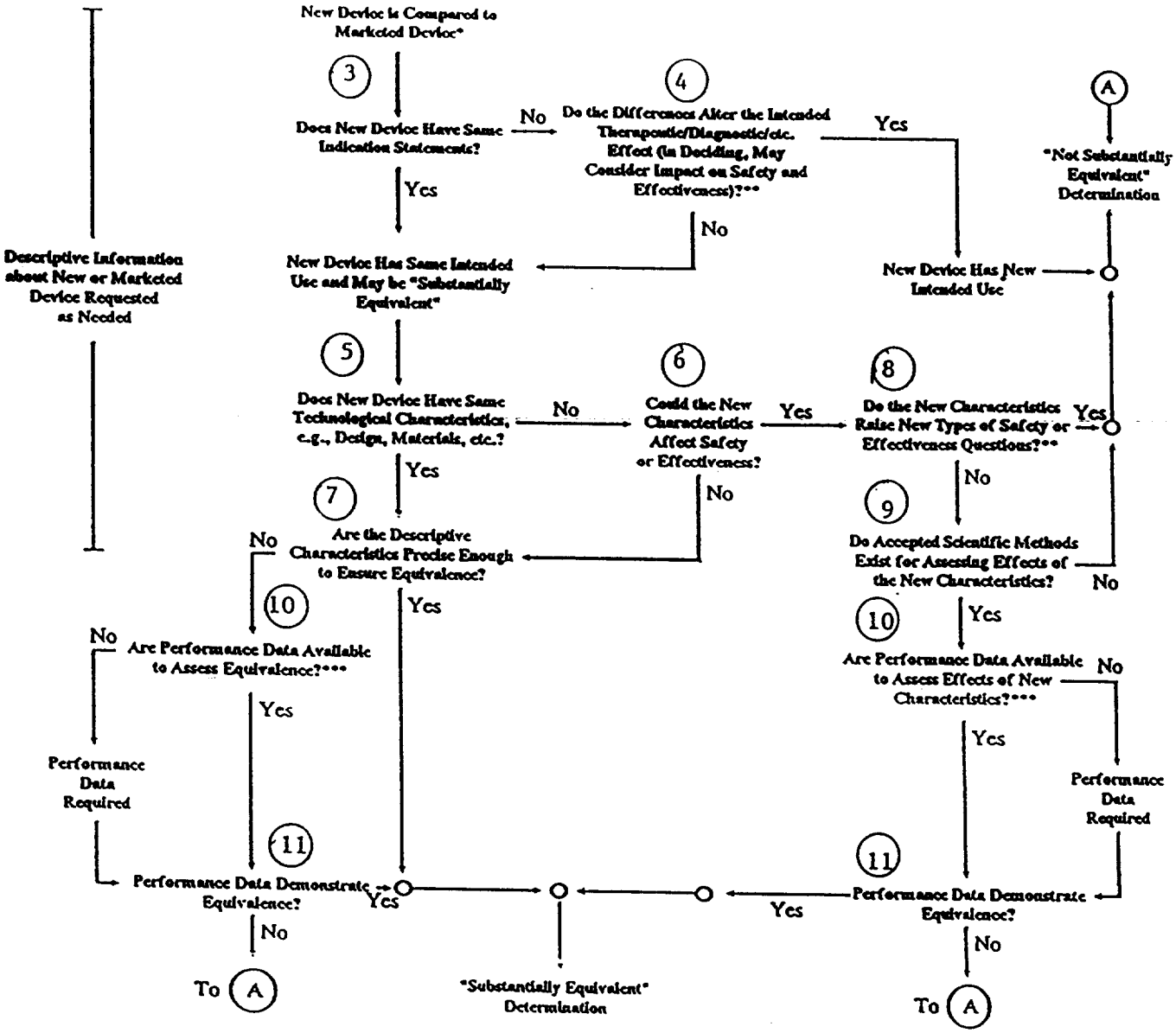
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

MEMORANDUM OF TELEPHONE CONVERSATION

(b)(5)

(b)(5)

21

(b)(5)

(b)(5)

(b)(5)

(b)(5)

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(b)(5)

(b)(5)

24

(b)(5)

(b)(5)

REVISED:01/22/96

PREMARKET NOTIFICATION (510(K)) CHECKLIST FOR ACCEPTANCE DECISION

_____ Device Name_____

Division/Branch_____

Administrative Reviewer Signature_____Date_____

Supervisory Signature_____Date_____

Did the firm request expedited review? _____Yes_____No

Did we grant expedited review? _____Yes_____No

Truthful and accurate statement enclosed?_____Yes_____No
(If Not Enclosed, Must Be A Refuse To Accept Letter)
Required For Originals Received 3/14/95 And After

Is the Indication for Use Form enclosed?_____YES_____No
(Required for Original 510(k)s received 1/1/96 and after -- must be submitted on a separate sheet of paper)

Without reviewing this 510(k), do you believe this device type may be a preamendments class III device? _____Yes_____No (IF YES, NOTIFY POS IMMEDIATELY IF THE OUTSIDE OF THE 510(k) HAS NOT BEEN STAMPED CLASS III SO THAT THE GMP INSPECTION CAN BE SCHEDULED AS SOON AS POSSIBLE). Class III devices can not receive a determination of substantial equivalence until the GMP inspection process has been completed.

Is this a file that was determined to be substantially equivalent by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? If so, a new ODE review is not required, please forward to POS.

_____Yes _____No

_____ Accepted

_____ Refuse To Accept

I. CRITICAL ELEMENTS:	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
A. Is The Product A Device?	☐	☐
B. Is The Device Exempt From 510(k) By Regulation Or Policy?	☐	☐
C. Is Device Subject To Review By CDRH?	☐	☐
D. (i) Are You Aware That This Device Has Been The Subject Of A Previous NSE Decision? (ii) If Yes, Does This New 510(k) Address The NSE Issue(s) (E.G., Performance Data)?	☐ ☐	☐ ☐
E. (i) Are You Aware Of The Submitter Being The Subject Of An Integrity Investigation? If Yes, Consult The ODE Integrity Officer. (ii) Has The ODE Integrity Officer Given Permission To Proceed With The Review? (Blue Book Memo #I91-2 And Federal Register 90N-0332, September 10, 1991.)	☐ ☐	☐ ☐
F. Does The Submission Contain The Information Required Under Sections 510(k), 513(f), And 513(i) Of The Federal Food, Drug, and Cosmetic Act (Act) And Subpart E Of Part 807 In Title 21 Of The Code Of Federal Regulations?:	☐	☐
1. Device Trade Or Proprietary Name	☐	☐
2. Device Common Or Usual Name Or Classification Name	☐	☐
3. Establishment Registration Number (Only Applies If Establishment Is Registered)	☐	☐
4. Class Into Which The Device Is Classified Under (21 CFR Parts 862 to 892)	☐	☐
5. Classification Panel	☐	☐
6. Action Taken To Comply With Section 514 Of The Act	☐	☐
7. Proposed Labels, Labeling And Advertisements (If Available) That Describe The Device, Its Intended Use, And Directions For Use (Blue Book Memo #G91-1)	☐	☐

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8. A 510(k) Summary Of Safety And Effectiveness Or A 510(k) Statement That Safety And Effectiveness Information Will Be Made Available To Any Person Upon Request	☐	☐
9. For Class III Devices Only, A Class III Certification And A Class III Summary	☐	☐
10. Photographs Of The Device	☐	☐
11. Engineering Drawings For The Device With Dimensions And Tolerances	☐	☐
12. The Marketed Device(s) To Which Equivalence Is Claimed Including Labeling And Description Of The Device	☐	☐
13. Statement Of Similarities And/Or Differences With Marketed Device(s)	☐	☐
14. Data To Show Consequences And Effects Of A Modified Device(s)	☐	☐
15. Truthful And Accurate Statement	☐	☐
II. Additional Information That Is Necessary Under 21 CFR 807.87(h):	☐	☐
A. Submitter's Name And Address	☐	☐
B. Contact Person, Telephone Number And Fax Number	☐	☐
C. Representative/Consultant If Applicable	☐	☐
D. Table Of Contents With Pagination	☐	☐
E. Address Of Manufacturing Facility/Facilities And, If Appropriate, Sterilization Site(s)	☐	☐
III. Additional Information That May Be Necessary Under 21 CFR 807.87(h):	☐	☐
A. Comparison Table Of The New Device To The Marketed Device(s)	☐	☐
B. Action Taken To Comply With Voluntary Standards	☐	☐
C. Performance Data	☐	☐
MARKETED DEVICE:	☐	☐
Bench Testing	☐	☐
Animal Testing	☐	☐
Clinical Data	☐	☐
NEW DEVICE:	☐	☐
Bench Testing	☐	☐
Animal Testing	☐	☐

Clinical Data	☐	☐
D. Sterilization Information	☐	☐
E. Software Information	☐	☐
F. Hardware Information	☐	☐
G. If This 510(k) Is For A Kit, Has The Kit Certification Statement Been Provided?	☐	☐
H. Is This Device Subject To Issues That Have Been Addressed In Specific Guidance Document(s)?	☐	☐
If Yes, Continue Review With Checklist From Any Appropriate Guidance Documents.	☐	☐
If No, Is 510(k) Sufficiently Complete To Allow Substantive Review?	☐	☐
I. Other (Specify)	☐	☐

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics ar not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 13, 1998

I-FLOW CORP.
20202 WINDROW DR.
LAKE FOREST, CA 92630
ATTN: ROBERT J. BARD, ESQ., R.A.C.

510(k) Number: K980558
Received: 13-FEB-1998
Product: PAINBUSTER INFUSION SYSTEM

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

I-FLOW
-FLOW
CORPORATION
Lake Forest, CA 92630
(800) 448-3569 (714) 206-2700
Fax (714) 206-2600

K980558

Premarket Notification - 510(k)

Via Federal Express
February 11, 1998

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center HFZ - 401
9200 Corporate Blvd.
Rockville, Maryland 20850

Reviewing Staff:

In accordance with §510(k) of the Federal Food, Drug, and Cosmetic Act and in conformance with Title 21 CFR §807.81, I-Flow Corporation is submitting this premarket notification for the *PainBuster*™ Infusion System, hereafter identified as PainBuster, prior to the introduction into interstate commerce for commercial distribution.

The *PainBuster* is an additional model to the Homepump elastomeric infusion pumps marketed by I-Flow Corporation. The *PainBuster* is substantially equivalent to the Pain Control Infusion Pump (PCIP) (K896422) marketed by Sgarlato Laboratories, Inc. The components of the *PainBuster* are substantially equivalent to the Homepump C-Series (K944692), Homepump Eclipse (K932740), B. Braun Perifix® Epidural Catheter Set, and Jelco™ Catheter Introducer Needle.

All questions and/or comments concerning this document should be made to:

Robert J. Bard, Esq., R.A.C.
Vice President Regulatory and Legal Affairs

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Telephone: 714.206.2700
Fax: 714.206.2600

Sincerely,

Robert J. Bard

Robert J. Bard, Esq., R.A.C.
Vice President Regulatory and Legal Affairs

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: 02/11/98	FDA Document Number:

Section A — Type of Submission

- ☒ 510(k)
- ☐ 510(k) Add'l information
- ☐ IDE
- ☐ IDE Amendment
- ☐ IDE Supplement
- ☐ IDE Report
- ☐ PMA
- ☐ PMA Amendment
- ☐ PMA Report
- ☐ PMA Supplement - Regular
- ☐ PMA Supplement - Special
- ☐ PMA Supplement - 30 day
- ☐ PMA Supplement - Panel Track

Section B1 — Reason for Submission — 510(k)s Only

- ☐ New device
- ☒ Additional or expanded indications
- ☐ Change in technology, design, materials, or manufacturing process
- ☐ Other reason (specify):

Section B2 — Reason for Submission — PMAs Only

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Change in ownership
- ☐ Change in correspondent
- ☐ Other reason (specify):
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Other (specify below)
- ☐ Process change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Response to FDA correspondence (specify below)
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment

RECEIVED 98 11 25 FDA/CDRH/ODE/DH

Section B3 — Reason for Submission — IDEs Only

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Emergency use:
  - ☐ Notification of emergency use
  - ☐ Additional information
- ☐ Other reason (specify):
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing
  - ☐ Protocol – feasibility
  - ☐ Protocol– other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting
- ☐ IOL submissions only:
  - ☐ Change in IOL style
  - ☐ Request for protocol waiver

3K-23

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	FDA Document Number:

Section C — Product Classification

Product code: 80 MEB	C.F.R. Section: 880.5725	Device class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification panel: General Hospital and Personal Use Device		

Section D — Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data: ☒ 510(k) summary attached ☐ 510(k) statement
1 80 MEB	2 80 FRN	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
(b)(4)	(b)(4)	

Section E — Product Information — Applicable to All Applications

Common or usual name or classification name:
Pump, Infusion, Elastomeric

Trade or proprietary or model name	Model number
1 PainBuster Infusion System	1 P065005, P125015, P125020
2	2
3	3
4	4
5	5
6	6

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☐ Human trials

Indications (from labeling):

The PainBuster is intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

	FDA Document Number:

Section F — Manufacturing / Packaging / Sterilization Sites

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 2026095	☒ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler

Company / Institution name: I-Flow Corporation

Division name (if applicable):	Phone number (include area code): (714) 206-2700
Street address: 20202 Windrow Drive	FAX number (include area code): (714) 206-2603

City: Lake Forest	State / Province: CA	Country: U.S.A.	ZIP / Postal Code: 92630

Contact name: Robert J. Bard, Esq., R.A.C.

Contact title: Vice President of Regulatory and Legal Affairs

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler

Company / Institution name:

Division name (if applicable):	Phone number (include area code): ( )
Street address:	FAX number (include area code): ( )

City:	State / Province:	Country:	ZIP / Postal Code:

Contact name:

Contact title:

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler

Company / Institution name:

Division name (if applicable):	Phone number (include area code): ( )
Street address:	FAX number (include area code): ( )

City:	State / Province:	Country:	ZIP / Postal Code:

Contact name:

Contact title:

	FDA Document Number:

Section G **Applicant or Sponsor**

Company / Institution name: I-Flow Corporation	FDA establishment registration number: 2026095
Division name (if applicable):	Phone number (include area code): (714) 206-2700
Street address: 20202 Windrow Drive	FAX number (include area code): (714) 206-2603

City	State / Province	Country	ZIP / Postal Code
Lake Forest	CA	U.S.A.	92630

Signature:

Name: Robert J. Bard, Esq., R.A.C.

Title: Vice President of Regulatory and Legal Affairs

Section H **Submission correspondent (if different from above)**

Company / Institution name:	
Division name (if applicable):	Phone number (include area code): ( )
Street address:	FAX number (include area code): ( )

City	State / Province	Country	ZIP / Postal Code

Contact name:
Contact title:

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

I-FLOW
CORPORATION
22102 Andrew Drive
Lake Forest, CA 92630
(800) 448-3569 (714) 206-2700
Fax (714) 206-2600

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As required by 21 CFR 807.87(j))

I certify that, in my capacity as the Vice President of Regulatory and Legal Affairs of I-Flow Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification for the PainBuster™ Infusion System are truthful and accurate and that no material fact has been omitted.

Signature

Robert J Bard, Vice President of Regulatory and Legal Affairs
Name Title

I-Flow Corporation 2/12/98
Company Dated

K980558
Premarket Notification (510(k) Number)

I-FLOW
CORPORATION
Lake Forest, CA 92630
(800) 448-3569 (714) 206-2700
Fax (714) 206-2600

510(k) Number (if known): K980558

Device Name: PainBuster™ Infusion System

Indications for Use:

1. The PainBuster is intended to provide continuous infusion of a local anesthetic directly into the intraoperative (soft tissue / body cavity) site for postoperative pain management.
2. The PainBuster is intended to deliver pain medication percutaneously via an administration set attached to a catheter.
3. The PainBuster is single use only.
4. The PainBuster is suitable for use as an ambulatory device and is intended for use in the home environment but not limited to use in the home environment.
5. The PainBuster is not intended for epidural, subcutaneous or vascular drug delivery.
6. The PainBuster is not intended for chemotherapy drugs.
7. No testing has been conducted to determine the efficacy of the PainBuster for the delivery of blood, blood products or TPN. The PainBuster is not intended for the delivery of blood, blood products or TPN.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUED ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

TABLE OF CONTENTS

Appendix A - PainBuster Infusion System Drawings

- PainBuster Pump and Catheter Drawings
- PainBuster Kit Drawing

Appendix B - PainBuster Infusion System Labeling

- PainBuster Directions for Use
- Pump Flow Rate Label 65 ml x 0.5 ml/hr
- Pump Flow Rate Label 125 ml x 1.5 ml/hr
- Pump Flow Rate Label 125 ml x 2 ml/hr
- Pump Pouch Label 65 ml x 0.5 ml/hr
- Pump Pouch Label 125 ml x 1.5 ml/hr
- Pump Pouch Label 125 ml x 2 ml/hr
- Lidstock Label 65 ml x 0.5 ml/hr
- Lidstock Label 125 ml x 1.5 ml/hr
- Lidstock Label 125 ml x 2 ml/hr
- PainBuster Box Label 65 ml x 0.5 ml/hr
- PainBuster Box Label 125 ml x 1.5 ml/hr
- PainBuster Box Label 125 ml x 2 ml/hr
- I-Flow Needle Label
- Jelco Needle Label
- I-Flow Catheter Label
- B. Braun Catheter Label
- B. Braun Catheter Directions for Use

Appendix C - Predicate Labeling

- Sgarlato Pain Control Infusion Pump
- I-Flow Homepump C-Series
- I-Flow Homepump Eclipse

Appendix D - References

Appendix E - Summary of Safety and Effectiveness

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1.0 GENERAL INFORMATION

1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to market an intraoperative site infusion kit, the PainBuster™ Infusion System, that utilizes legally marketed components for a new intended use.

1.1.2 Trade Name: PainBuster™ Infusion System

1.1.3 Common Name: Elastomeric Infusion Pump

1.1.4 Classification Name: Pump, Infusion, Elastomeric

1.1.5 Product Code: 80 MEB

1.1.6 Device Classification: Class II, 880.5725

1.1.7 Classification Panel: General Hospital and Personal Use Device

1.2 Statement of Equivalence

1.2.1 The PainBuster Infusion System is a kit which includes components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation).

1.2.2 The PainBuster Infusion System is substantially equivalent in intended use to the Pain Control Infusion Pump (PCIP) (K896422) distributed by Sgarlato Laboratories, Inc.

1.2.2.1 The Sgarlato PCIP kit contains an infusion pump produced by Burron/B. Braun, B. Braun catheter and Jelco needle.

1.2.2.2 The catheter and needle included in the PainBuster kit are separately purchased pre-amendment or 510(k) devices similar to the devices in the Sgarlato PCIP kit.

1.2.2.2.1 An example of the catheter included in the PainBuster kit is the B. Braun Perifix® Epidural Catheter Set.

1.2.2.2.2 An example of the needle included in the PainBuster kit is the Jelco™ Catheter Introducer Needle.

1.2.2.2.3 The PainBuster pump is substantially equivalent to the Homepump C-Series (K944692) and Homepump Eclipse (K932740) marketed by I-Flow Corporation.

1.2.2.3 The PainBuster pump's design is nearly identical to the original Homepump C-Series, see section 2.1 below.

12

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50

5.2 Drug Stability

5.2.1 There are no drugs included in the PainBuster Infusion System.

6.0 INTENDED USE

6.1 The PainBuster is intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

6.2 The PainBuster is intended to deliver pain medication percutaneously via an administration set attached to a catheter.

6.3 The PainBuster is not intended for epidural, subcutaneous or vascular drug delivery.

6.4 The PainBuster is single use only.

6.5 No testing has been conducted to determine the efficacy of the PainBuster for the delivery of blood, blood products or TPN. The PainBuster is not intended for the delivery of blood, blood products or TPN.

6.6 The PainBuster is suitable for use as an ambulatory device and is intended for use in the home environment but not limited to use in the home environment.

7.0 LABELS AND LABELING

7.1 I-Flow Corporation believes the proposed labels and labeling, where appropriate, meets the requirements of 21 CFR Part 801 as it relates to a determination of intended use and adequate directions for use.

7.2 The PainBuster Directions for Use labeling:

7.2.1 Provides comprehensive directions for preparation and use for the PainBuster.

7.2.2 Contains warning information.

7.2.3 Contains the prescription statement required under 801.109 (b)(1).

7.2.4 Includes the specifications of the PainBuster. The specifications include the priming volume, residual volume, accuracy and operating conditions.

7.3 Identification labels and labeling

7.3.1 I-Flow has developed product identification labeling for the PainBuster Infusion System. Refer to Appendix B for examples.

7.4 Packaging labels

7.4.1 Contains the prescription statement required under 801.109(b)(1).

7.5 Appendix B contains example labeling of the following:

7.5.1 I-Flow labeling for catheter and needle.

7.5.2 B. Braun Perifix® Epidural Catheter Set.

7.5.3 Jelco™ 14 G Catheter Introducer Needle.

7.6 Appendix C contains predicate labeling for the Sgarlato Pain Control Infusion Pump (PCIP), Homepump C-Series and Homepump Eclipse.

8.0 REFERENCES

8.1 Appendix D contains the following articles:

8.1.1 "Local Anaesthetic Techniques for Prevention of Postoperative Pain" by E. N. Armitage.

8.1.2 "Continuous Infusion Techniques for Postoperative Pain Relief" by John H. McClure.

8.1.3 "Wound Infiltration with Local Anaesthetics for Postoperative Pain Relief" by J. B. Dahl, S. Moiniche, and H. Kehlet.

8.1.4 "Bupivacaine Infusion for Iliac Crest Donor Sites" by R. A. Wilkes, and W. G. Thomas.

8.1.5 "Postoperative Patient Controlled Regional Analgesia at Home" by N Rawal, MD, PhD, J Hylander, RN, R Allvin, CRNA, J Hallén, MD, K Axelsson, MD, PhD, A Amilon, MD, and G Lidegran, MD.

8.1.6 "Postoperative Patient-Controlled Local Anesthetic Administration at Home" by Narinder Rawal, MD, PhD, Kjell Axelsson, MD, PhD, Jan Hylander, RN, Renée Allvin, CRNA, Anders Amilon, MD, Gunnar Lidegran, MD, and Jan Hallén, MD.

8.1.7 "Pleural Anesthetics Given Through an Epidural Catheter Secured Inside a Chest Tube" by Joseph W. Baker, MD, and Curtis G. Tribble, MD.

9.0 STANDARDS

9.1 There are currently no standards established for elastomeric infusion pumps.

10.0 PACKAGING

10.1 The PainBuster kit components are packaged individually in either sterile Tyvek® pouches or sterile Form/Fill/Seal trays. The components of the kit are packaged in a sealed tray.

10.1.1 Packaging is suitable for either radiation or ETO sterilization.

10.2 The PainBuster Infusion System will be packaged 6 kits per case.

10.3 Package aging tests have been conducted on the individual components packaging material. The results of bacterial dust challenge testing has determined that the Tyvek® pouches and Form/Fill/Seal trays used to package the disposable PainBuster pump maintains sterility in excess of three years.

11.0 STERILIZATION INFORMATION

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(b)(4)

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(b)(4)

(b)(4)

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(b)(4)

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(b)(4)

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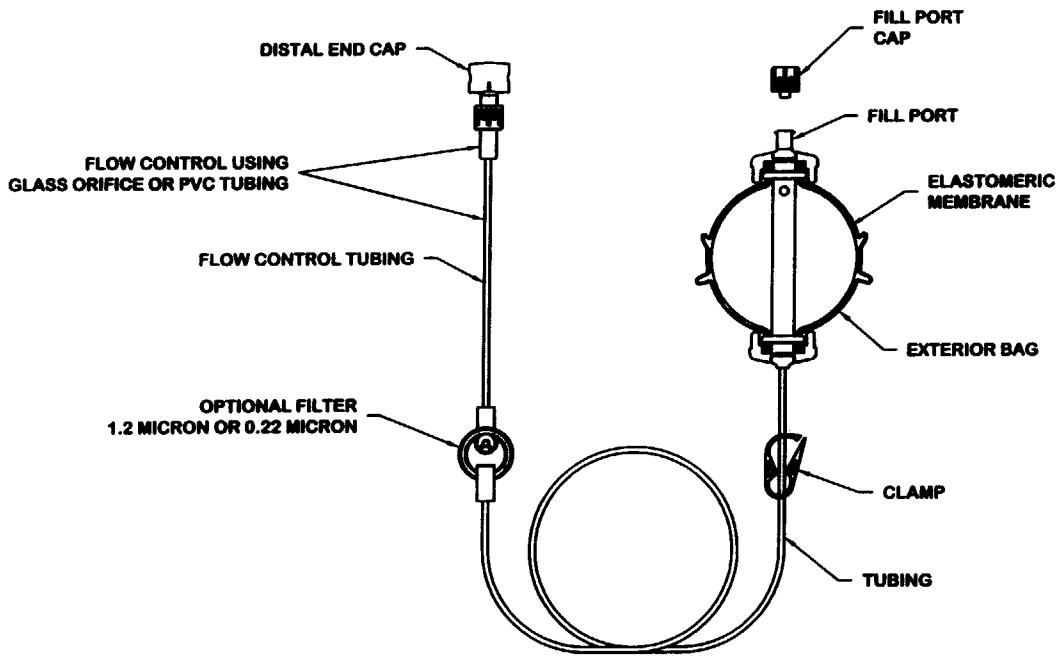
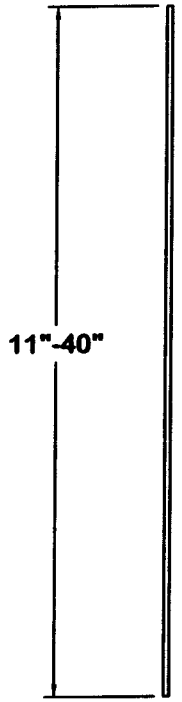
Appendix A

PainBuster Insfusion System Drawings



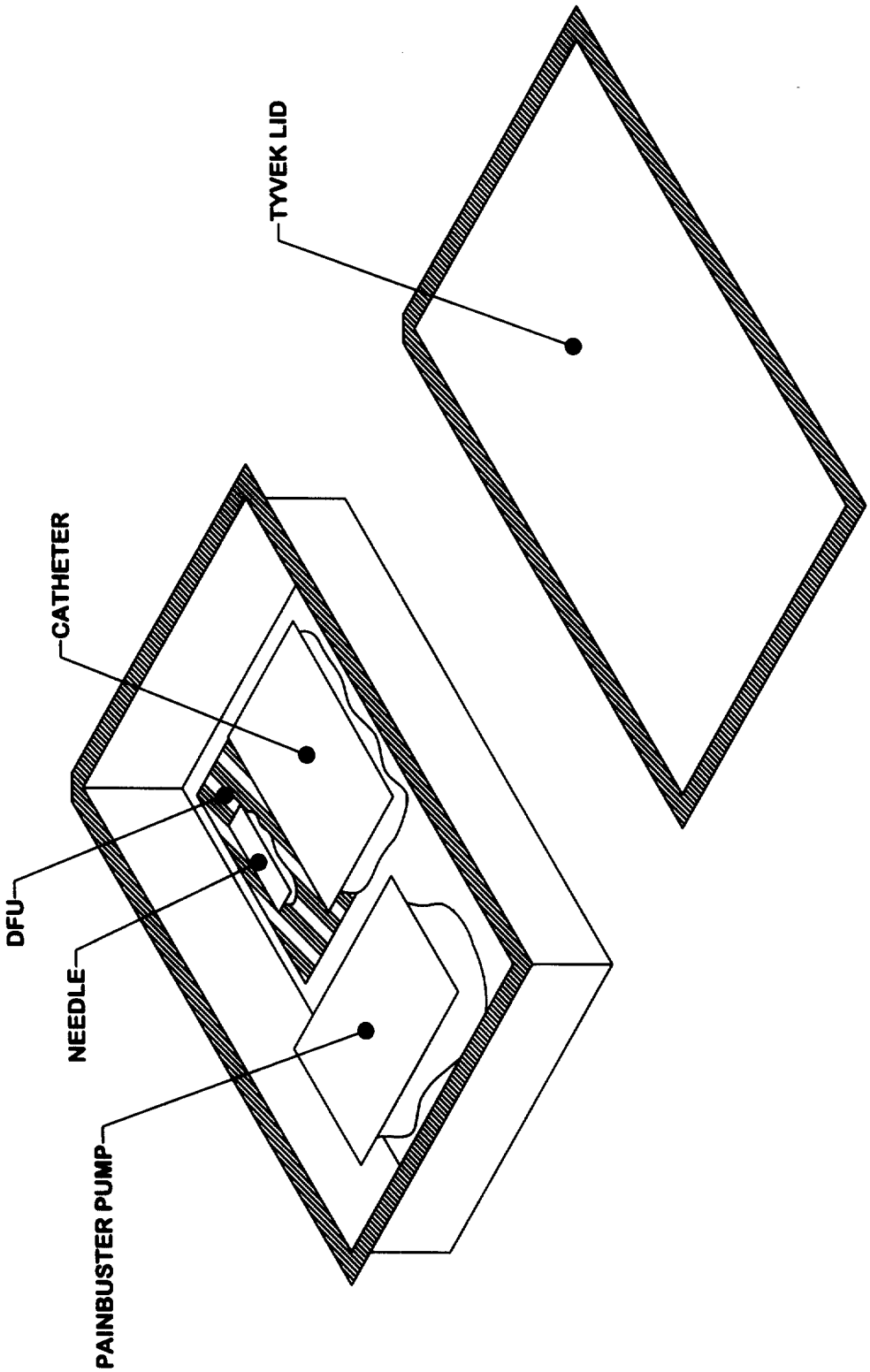
PAINBUSTER PUMP



20G CATHETER

NOTE:
OPTION OPEN END OR
CLOSED END LATERAL HOLE

89


TYVEK LID
CATHETER
DFU
NEEDLE
PAINBUSTER PUMP

Appendix B

PainBuster Insfusion System Labeling

60

DIRECTIONS FOR USE

PainBuster™ Infusion System

INTENDED USE
The PainBuster is intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

CONTRAINDICATIONS
This system is not designed for epidural, subcutaneous or vascular drug delivery. Not for blood, blood products or TPN use. Not for chemotherapy drugs.

WARNINGS
- Single Use Pump. Do not refill. Discard after use.
- Do not overfill the pump. Follow manufacturer recommendations for filling.
- Medications being used with this system should be used in accordance with instructions provided from manufacturer.

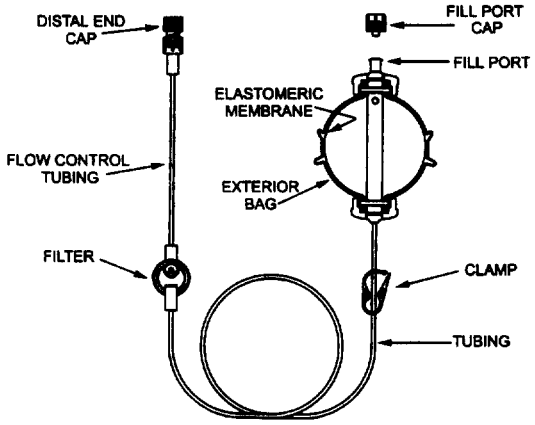
DIRECTIONS FOR USE
Use Aseptic Technique

FILLING THE ELASTOMERIC PUMP
1. Close clamp on tubing.
2. Remove protective cap from filling port.
3. Attach filled Syringe to the fill port and inject into pump. Repeat if necessary. Do not fill over 65ml or 125ml as applicable. Replace fill port cap.
4. To prime the tubing, open the clamp on the tubing and allow fluid to fill the tubing. Close clamp until ready for use.
5. If necessary, attach connector to the catheter. Tighten until catheter cannot be removed.
6. Attach the connector of the catheter to the pump tubing.
7. Open the clamp for approximately 10 minutes to prime catheter, and then close the clamp.

PLACING THE CATHETER
1. Insert introducer needle through the skin into the surgical wound site.
2. Insert the catheter through the introducer needle and into the wound site.

Note: Do not place catheter into blood vessel.

3. Remove introducer needle and tape catheter securely in place.



STARTING THE PAIN RELIEVER SYSTEM
1. Open the clamp to begin delivering medication.
2. Apply desired dressing.
3. Secure Pain Control System to the outer dressing with tape as desired.

SPECIFICATIONS
1. Set priming/residual volume is less than 5 ml .
2. Delivery accuracy is ±15% (at a 95% confidence level) of the labeled infusion period when delivering saline at 88°F (31° C).

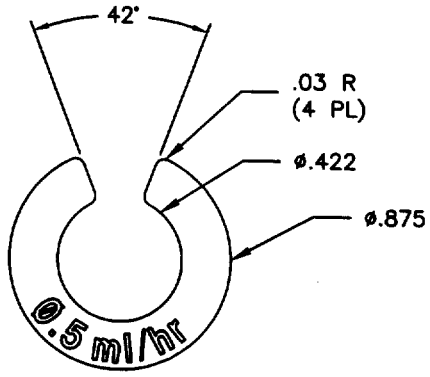
NOTES:
1. The infusion times for each administration set are indicated on the administration set label.
2. Actual infusion times may vary from the labeled infusion period due to:
   -viscosity and/or drug concentration.
   -positioning the Painbuster above (decrease) or below (increase) the catheter site.
   Note: The magnitudes of these effects have not been quantified.
3. This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

Infusion is complete when the Elastomeric pump is no longer extended.

CAUTION
Federal (USA) law restricts this device to sale by or the order of a healthcare professional.

A PRODUCT OF
I-FLOW
I-FLOW CORPORATION
LAKE FOREST, CA 92630
U.S.A.

1301891A
2/98



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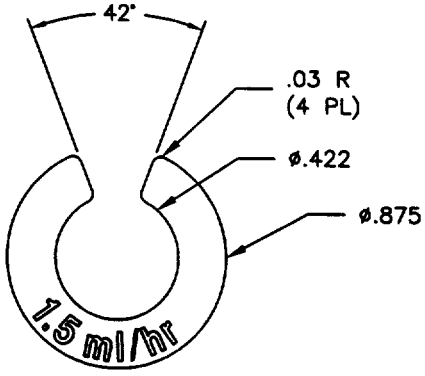

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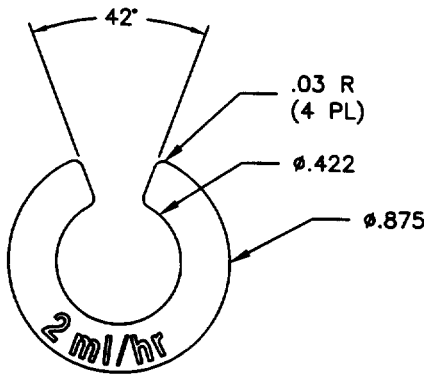

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I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

CONTENTS / INHALT / CONTENU / CONTENIDO: 1

REF P065005
PART NO. 5001060

PainBuster™ Infusion Pump
65 ml Volume, 0.5 ml/hr




SEE DIRECTIONS FOR USE.
CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL.

Manufactured by / Hersteller von /
Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

CE 0123

European Representative / Europaische Vertretung /
Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

1301897A

65

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I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

CONTENTS / INHALT / CONTENU / CONTENIDO: 1

REF P125015
PART NO. 5001061

PainBuster™ Infusion Pump
125 ml Volume, 1.5 ml/hr




SEE DIRECTIONS FOR USE.
CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL.

Manufactured by / Hersteller von / Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

CE 0123

European Representative / Europaische Vertretung / Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

1301898A

66

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I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

CONTENTS / INHALT / CONTENU / CONTENIDO: 1

REF P125020
PART NO. 5001062

PainBuster™ Infusion Pump
125 ml Volume, 2 ml/hr

SEE DIRECTIONS FOR USE.
CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL.

Manufactured by / Hersteller von /
Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

CE 0123

European Representative / Europaische Vertretung /
Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

1301899A

67

PainBuster™ Infusion System

REF P065005
65 ml x 0.5 ml/hr

Contents of unopened, undamaged package are:
STERILE

DISPOSABLE - Destroy after single use.
Do not clean or resterilize.
Store at controlled room temperature.

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a healthcare professional.

REFER TO OPERATING INSTRUCTIONS PRIOR TO USE.

ONE SYSTEM CONTAINING:
- 65 ml PainBuster Infusion Pump
- 20 G x 39 ½ in. PainBuster Catheter
- 14 G x 2 ½ in. PainBuster Catheter Introducer Needle

Manufactured By:
I-FLOW CORPORATION
Lake Forest, CA 92630
U.S.A.

U.S. Pat. Nos. D324,911; 5,080,652; 5,105,983; and Foreign Pat. Pend.

LOT NO.:
USE BEFORE:

1301892A

PEEL TO OPEN

68

PainBuster™ Infusion System

REF P125015
125 ml x 1.5 ml/hr

Contents of unopened, undamaged package are:
STERILE

DISPOSABLE - Destroy after single use.
Do not clean or resterilize.
Store at controlled room temperature.

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a healthcare professional.

REFER TO OPERATING INSTRUCTIONS PRIOR TO USE.

ONE SYSTEM CONTAINING:
- 125 ml PainBuster Infusion Pump
- 20 G x 39 ½ in. PainBuster Catheter
- 14 G x 2 ½ in. PainBuster Catheter Introducer Needle

Manufactured By:
I-FLOW CORPORATION
Lake Forest, CA 92630
U.S.A.

U.S. Pat. Nos. D324,911; 5,080,652; 5,105,983; and Foreign Pat. Pend.

LOT NO.:
USE BEFORE:

1301900A

PEEL TO OPEN

69

PainBuster™ Infusion System

REF P125020
125 ml x 2 ml/hr

Contents of unopened, undamaged package are:
STERILE

DISPOSABLE - Destroy after single use.
Do not clean or resterilize.
Store at controlled room temperature.

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a healthcare professional.

REFER TO OPERATING INSTRUCTIONS PRIOR TO USE.

ONE SYSTEM CONTAINING:
- 125 ml PainBuster Infusion Pump
- 20 G x 39 ½ in. PainBuster Catheter
- 14 G x 2 ½ in. PainBuster Catheter Introducer Needle

Manufactured By:
I-FLOW CORPORATION
Lake Forest, CA 92630
U.S.A.

U.S. Pat. Nos. D324,911; 5,080,652; 5,105,983; and Foreign Pat. Pend.

LOT NO.:
USE BEFORE:

1301901A

PEEL TO OPEN

70

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I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

CONTENTS / INHALT / CONTENU / CONTENIDO: 6

REF P065005

PART NO. 5001060

PainBuster™ Infusion System
65 ml Volume, 0.5 ml/hr



STERILE

LOT

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL. SEE DIRECTIONS FOR USE.

Manufactured by / Hersteller von /
Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

CE
0123

European Representative / Europaische Vertretung /
Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

1301894A

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I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

CONTENTS / INHALT / CONTENU / CONTENIDO: 6

REF P125015

PART NO. 5001061

PainBuster™ Infusion System
125 ml Volume, 1.5 ml/hr

STERILE

LOT

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL. SEE DIRECTIONS FOR USE.

Manufactured by / Hersteller von /
Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

CE 0123

European Representative / Europaische Vertretung /
Représentant pour l'Europe / Representante Europeo:
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Borngasse 20, 35619 Braunfels, Germany

1301895A

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I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

CONTENTS / INHALT / CONTENU / CONTENIDO: 6

REF P125020

PART NO. 5001062

PainBuster™ Infusion System
125 ml Volume, 2 ml/hr

STERILE

LOT

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL. SEE DIRECTIONS FOR USE.

Manufactured by / Hersteller von /
Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

CE
0123

European Representative / Europaische Vertretung /
Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

1301896A

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SINGLE USE ONLY • READ INSTRUCTIONS • SINGLE USE ONLY • READ INSTRUCTIONS

14 G
2 ¼ in.
(57mm)

I-Flow Needle

REF 5001000
I-Flow Corporation
Lake Forest, CA 92630
U.S.A.

1301000A

STERILE UNLESS OPENED OR DAMAGED • STERILE UNLESS OPENED OR DAMAGED

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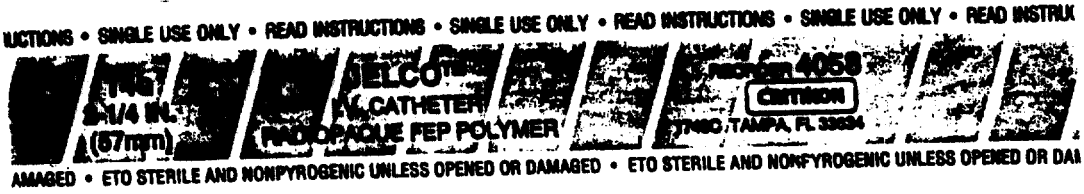
JELCO
IV CATHETER
RADIOPAQUE FEP POLYMER
CRITICON
AMAGED • ETO STERILE AND NONPYROGENIC UNLESS OPENED OR DAMAGED • ETO STERILE AND NONPYROGENIC UNLESS OPENED OR DA

PEEL OPEN

PEEL OPEN

I-Flow Catheter Set

Contents of unopened, undamaged package are:
STERILE

Contents:
One - 20 G x 39.3 in. (100 cm)
Open End Catheter
One - Screw Cap Luer Lock
Catheter Connector

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a healthcare professional.

REF 5000999

DISPOSABLE - Destroy after single use. Do not clean or resterilize.
Store at controlled room temperature.

I-Flow Corporation
Lake Forest, CA 92630
U.S.A.

1300999A

EXP

LOT

96

PEEL OPEN

PERIFIX PERIFIX PERIFIX

PEEL OPEN

PERIFIX®
Epidural Catheter Set

PRODUCT CODE
EC20-C
333530

Contents of unopened, undamaged package are:
STERILE

CONTENTS:
One - Marked 20 GA. x 39.3 in. (100 cm) Radiopaque Polyamide Epidural Catheter with Closed Tip and Three Lateral Sideports
One - Catheter Threading Assist Guide
One - Screw Cap Luer Lock Catheter Connector

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

DISPOSABLE - Destroy after single use. Do not clean or resterilize.
Store at controlled room temperature.

B|BRAUN

B. Braun Medical Inc.
Bethlehem, PA 18018
Assembled and packaged in U.S.A.
Components made in U.S.A. and Germany

P-2680 REV. 3/95

891430 EXP 1/02

PERIFIX® Epidural Catheter Directions

Contents of unopened, undamaged package are:

STERILE

DISPOSABLE - Destroy after single use. Do not clean or resterilize.
Store at controlled room temperature.

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

DIRECTIONS: Use Aseptic Technique.

Following puncture and verification of the Epidural Space, introduce the catheter tip through the Epidural Needle using the:

(1) Threading Assist Guide. The guide will increase longitudinal stability of the catheter.

CAUTION: DO NOT WITHDRAW CATHETER THROUGH NEEDLE BECAUSE OF THE POSSIBLE DANGER OF SHEARING.

Insert catheter to desired depth. Catheter markings: 5.5 cm (1 ring)... 10.5 cm (2 rings)... 15.5 cm (3 rings) in 1 cm increments. 20.5 cm (4 rings). The solid wide warning mark indicates exit of catheter from needle when using the Threading Assist Guide and a PERIFIX® Epidural Needle. The catheter will exit 1 cm before the warning mark when not using the Threading Assist Guide.

Remove needle and Threading Assist Guide over catheter while holding catheter tightly in place.

(2) Introduce distal end of catheter as far as possible in central opening of transparent screw cap of catheter connector.

(3) Tighten screw cap until catheter can no longer be withdrawn. Administer test dose. Administer anesthetic as needed.

B|BRAUN

B. Braun Medical Inc.
Bethlehem, PA 18018

A4806076 P-3050 REV. 8/95

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Appendix C
Predicate Labeling

Sgarlato Pain Control Infusion Pump Predicate Labeling

The following contains example labeling from the Sgarlato Pain Control Infusion Pump:

- Directions for Use
- Kit Tray Label
- Special Instructions
- Abbrev. Pain Control Infusion Pump Instructions
- Pain Control Infusion Pump Patient Instructions
- Pain Control Infusion Pump Medical Necessity
- Background and Significance of Pain Control Infusion Pump - "PCIP"
- Brochure, "A Significant Improvement in Portable Infusion"
- More background information on Pain Control Infusion Pump
- B. Braun Medical Engineering Memo

Pain Control Infusion Pump

Pain Control System

DESCRIPTION

The Pain Control Infusion Pump is a complete, lightweight, disposable device which uses a constant internal pressure to infuse medication for control of pain. The system is designed to deliver medication continuously into the surgical wound site over the infusion period.

INDICATIONS

The system is indicated for the relief of pain in patients following surgery, by the continuous administration of medication into the wound site. It is convenient for use by ambulatory patients.

CONTRAINDICATIONS

Not intended for intravenous infusion.

WARNINGS

DISPOSABLE - Destroy after single use. Do not refill or resterilize.
Do not overfill device.
Follow drug manufacturer's instructions for the medication being used.

CAUTION

Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

DIRECTIONS FOR USE:

Use Aseptic Technique.

FILLING RESERVOIR PUMP

1. Close on/off clamp of medication tubing.
2. Remove protective cover from female luer lock filling port and discard.
3. Attach 60 ml syringe without needle to filling port at the top of the Pump Reservoir (refer to figure 1.). Fill reservoir with up to 100 ml of medication.
4. Once filling is complete, remove syringe. Securely attach blue replacement cap to filling port to maintain a sterile filling port.

PRIMING SYSTEM (refer to figure 3a.)

1. Attach clear connector to medication catheter by pushing catheter into connector as deeply as possible. Twist connector as tightly as possible, use **MAXIMUM HAND FORCE** to screw connector components together to assure that the catheter will not pull out. It is almost impossible to constrict the catheter flow by maximum tightening.
2. Hold system reservoir and filter in upright position. Loosen proximal luer connector (green) to allow trapped air to exit.
3. Open on/off clamp (solution will automatically begin to flow into tubing and catheter). (Tighten proximal luer connector when fluid flow without air reaches connector.)
4. Hold the filter vertically and tap filter lightly to remove air bubbles.
5. Keep priming until all air has been purged from tubing, filter and catheter.
6. Allow 10 minutes before placing catheter in patient to see medication drops flow to the end of the medication catheter. If flow is not seen, attempt priming with 60 ml syringe filled with 10 ml or more of medication. Clamp off tubing with pinch clamp. Disconnect proximal luer connector and attach distal connection to syringe. Aspirate air bubbles and then force medication distally until drops of medication are seen at distal end of medication catheter. If flow is not seen, discard unit and repeat above steps with new Pain Control Infusion Pump unit. If flow is seen, reattach proximal connector and release pinch tubing clamp.

PLACING CATHETER (refer to figure 2.)

NOTE: Prime system completely prior to placing catheter.

METHOD A: FROM INSIDE THE WOUND

1. Push introducer needle from the surgical wound site subcutaneously and puncture through skin at a desired location away from the surgical wound site.
2. Thread open end of catheter through the tip of the catheter introducer needle at the puncture site until the catheter is seen in the surgical wound site.
3. Place the end of the catheter in an appropriate location (not in a vessel) within the surgical wound site.
4. Tape catheter to the skin to prevent the catheter from pulling out of the wound site. It is most effective to tape in a linear parallel manner to the catheter (refer to figure 3.)
5. Remove introducer needle from wound site leaving catheter in place and dispose of needle in accordance with institutional protocol.

METHOD B: INSERTION THROUGH SKIN

1. Puncture introducer needle through the skin at a desired location external to the surgical wound site; push the introducer needle subcutaneously into the surgical wound site.
2. The catheter is left free, unattached from the connector. Push catheter into the hub end of the needle and allow catheter to exit at the needle tip into the surgical wound site.
3. Remove introducer needle and tape catheter as described in Method A steps 4 and 5 above.
4. Attach catheter to clear connector per Priming System Procedure Step 1.

figure 1.

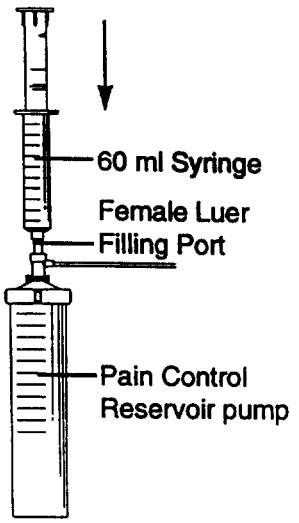


figure 2.

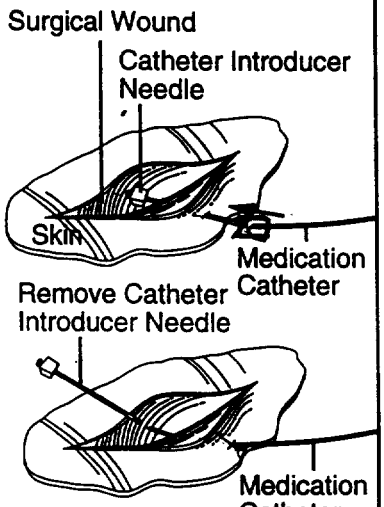
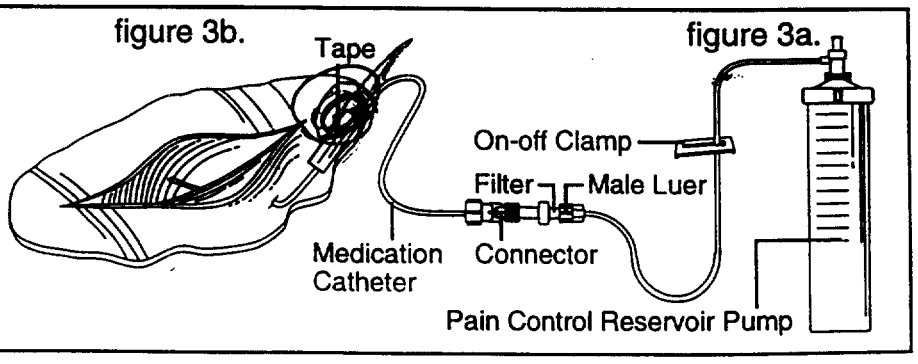


figure 3b.

figure 3a.



Manufactured for:
SGARLATO LABORATORIES, INC.
237 ALMENDRA AVE.
LOS GATOS, CA 95030
Phone 1-800-421-5303
1-408-399-4638
Fax 1-408-354-4922

A4806164 P-2143-3 REV. 1/97

87

Pain Control Infusion Pump

Pain Control System

Pain Control System

for continuous delivery of medication for control of pain

RATE: Approximately 2.0 ml/hr

PRODUCT CODE:
PC2000-40

Contents of unopened, undamaged package are:
STERILE • NONPYROGENIC

DISPOSABLE - Destroy after single use.
Do not clean or resterilize.
Store at controlled room temperature.

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

REFER TO OPERATING INSTRUCTIONS PRIOR TO USE.

U.S. PATENTS 4,997,420 AND 5,078,679 AND OTHER PATENTS PENDING

ONE SYSTEM CONTAINING:

- 100 ml Medication Reservoir Pump
- 34 inch Medication Tubing
- 5 micron Medication Filter and Flow Regulator
- 39-1/2 inch Medication Catheter
- 18 GA. x 2-1/2 in. Catheter Introducer Needle
- 60 ml Syringe
- Catheter Tape
- Replacement Cap
- Carrying Harness

Manufactured for
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1-408-399-4638
Fax 1-408-354-4922

A1 09/92 E-2541-1 REV 1-12

Pain Control Infusion Pump
Pain Control System

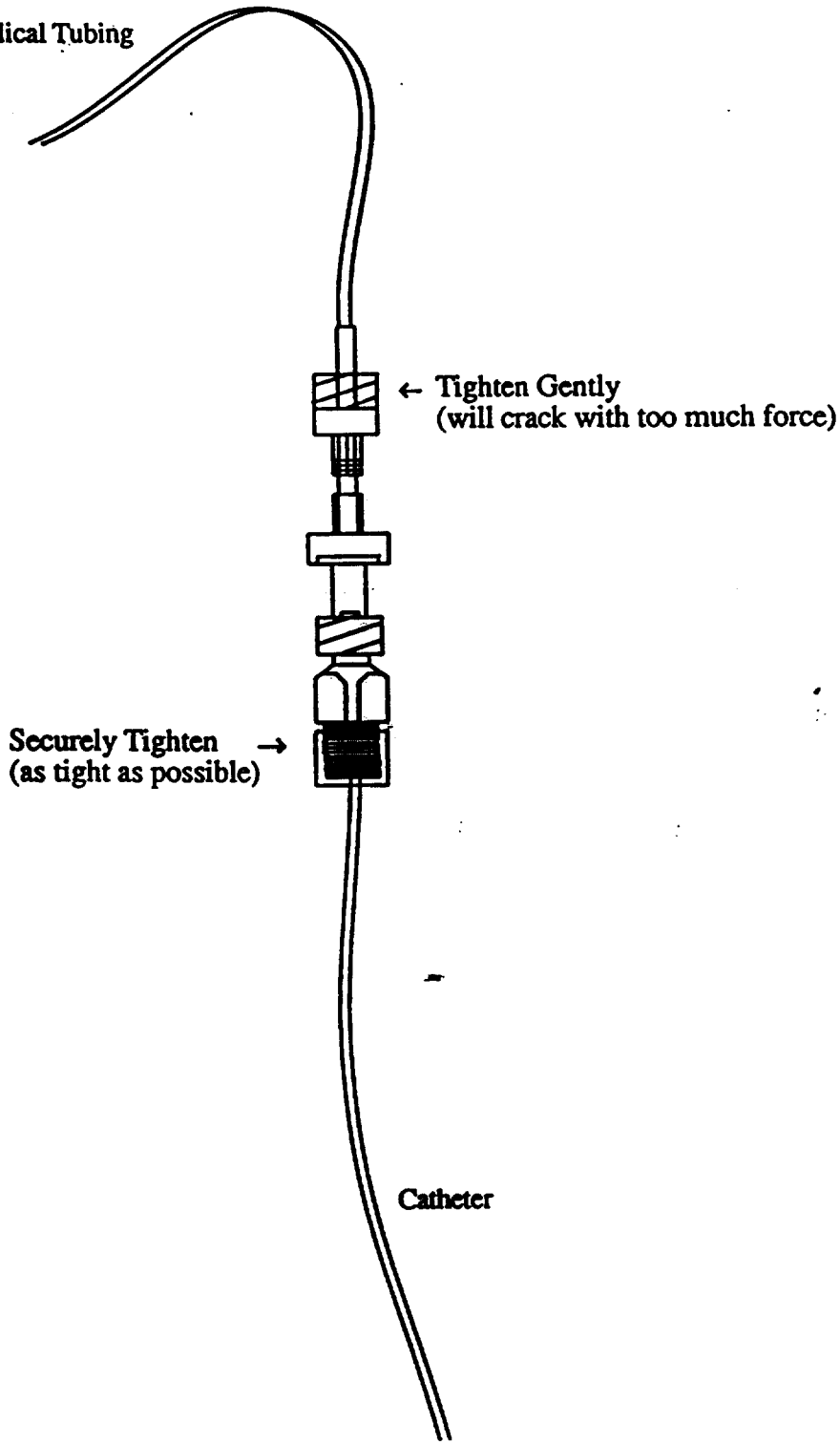
LOT NO.: 914420

PEEL TO OPEN

PRODUCT CODE:
PC2000-40

82

Special Instructions: Please Review



ABBREV. PAIN CONTROL INFUSION PUMP INSTRUCTIONS

Additional information is provided inside the sterile kit.

IMPORTANT: Use aseptic technique.
RECOMMENDED: Administer prophylactic antibiotic.

FILLING RESERVOIR PUMP:

1. Disconnect flow regulator from tubing at green male luer.
2. Close on/off clamp at the very end of tubing (next to green male luer).
3. Draw medication into 60 ml syringe. Remove air bubbles.
4. Remove and discard protective cap on top of reservoir filling port.
5. Attach 60 ml syringe without needle to reservoir filling port and load up to 100 ml of medication.
6. Remove syringe and attach blue replacement cap to filling port.
7. Prime reservoir and tubing by briefly opening clamp to let air bubbles out.
8. Connect flow filter to tubing. Do not tighten excessively. Open clamp.

PLACEMENT OF CATHETER:

1. Puncture blue introducer needle through the skin external to the surgical wound site. Push needle subcutaneously into the wound cavity.
2. Feed micro catheter through needle and allow catheter to exit at the needle tip into the wound at the desirable surgical plane.
IMPORTANT: Do not put catheter in blood vessel.
3. Remove and discard needle, leaving catheter in place.
4. Tape catheter to body very near to the insertion site utilizing the 3-4 loop technique in order to keep catheter securely in place.
5. Insert catheter as deeply as possible (apx. 1/2 inch) into connector. Twist connector as **TIGHTLY AS POSSIBLE** to assure that catheter will not pull out.
6. Tape connector below patient's knee (if procedure is below the knee). **RECOMMENDED:** Place gauze pad between body and connector for comfort.
7. Attach carrying harness to reservoir. Patients can wear or carry device however they prefer.

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PAIN CONTROL INFUSION PUMP PATIENT INSTRUCTIONS

The PCIP Pain Control System is a portable infusion pump designed to deliver medication directly to the surgical site for management of pain.

How the System Works

PCIP administers local pain medication directly to the pain site via a tiny tube which is placed inside the wound by the physician during surgery. Pain relief is provided directly where it is needed. This is an alternative to other forms of therapy such as pain killers and narcotics taken orally which go throughout the entire body and sometimes cause side effects such as drowsiness, disorientation, nausea or other adverse reactions.

PCIP is comprised of a reservoir with internal spring pressure, tubing and a very precise flow regulator. The device has been filled with medication to flow continuously for a specific period of time. The system should remain completely intact for the duration of the period. Do not remove the blue cap or disconnect the device in any way.

If Complications Arise

If you experience any problems with the PCIP unit such as leakage, the device becoming disconnected, the tube pulling out of the wound site, or if you experience discomfort or excessive pain, call your physician immediately. He/she may prescribe supplemental medication if necessary.

There is a white clamp on the thicker tubing to restrict the fluid flow if necessary. This should be done only upon the direction of your doctor. As a general rule, you do not have to do anything with the unit because it is fully self contained and automatic.

PAIN CONTROL INFUSION PUMP Medical Necessity

Postoperative pain management is an important concern for anesthesiologists and surgeons. Adequate pain control has been shown to reduce morbidity by improving mobility and decreasing the risk of developing deep venous thrombosis. Patient satisfaction is also increased with control of postoperative pain.

Systematic drugs such as narcotics can provide analgesia but often have side effects such as respiratory depression, excessive sedation nausea and vomiting. Regional anesthesia with local anesthetic reduces the need for systematic medications but requires a pain injection and repeated dosing.

Local infiltration of a surgical incision with a local anesthetic has been shown to provide adequate anesthesia. Techniques used include bathing the incision with local anesthetic prior to closure (provides limited duration of pain relief), repeated injections into wound (painful, increased risk of wound infection and time-consuming and placement of an epidural catheter into the wound to allow repeated boluses of local anesthetic. The last technique still requires additional time from the care given to provide the additional doses.

The Pain Buster infusion pump is a cost effective ambulatory, disposable elastomeric pump designed to continuously deliver a local anesthetic (Bupivacaine 0.25%). It has been developed to produce analgesia for the control of excruciating postoperative pain.

* * *

Background and Significance of Pain Control Infusion Pump - "PCIP"

Post-operative pain management is an important concern for anesthesiologists and surgeons. Adequate pain control has been shown to reduce morbidity by improving mobility and decreasing the risk of developing deep venous thrombosis. Patient satisfaction is also increased with control of post-operative pain.

Systemic drugs such as narcotics can provide analgesia but often have side effects such as respiratory depression, excessive sedation, nausea and vomiting. Regional anesthesia with local anesthetic reduces the need for systemic medications but requires a painful injection and repeated dosing.

Local infiltration of a surgical incision with a local anesthetic has been shown to provide adequate anesthesia. Techniques used include bathing the incision with local anesthetic prior to closure (provides limited duration of pain relief), repeated injections into the wound (painful, increased risk of wound infection and time-consuming) and placement of an epidural catheter into the wound to allow repeated boluses of local anesthetic. This last technique still requires additional time from the care giver to provide the additional doses.

The PCIP medication infusion pump is a cost effective ambulatory, disposable, spring activated pump designed to continuously deliver a local anesthetic (Bupivacaine 0.25%). It has been developed to produce analgesia for the control of excruciating post-operative pain.

PCIP is assembled aseptically in a Clean Room (Class 100). It consists of simple assembly of components already used in medical devices. A spring is mounted on a syringe plunger and capped by an outer shell. Medical grade PVC tubing is connected to the syringe. A micro-glass cannula is placed in the end of the PVC tubing exiting the connector. A catheter is connected to the end of the PVC tubing. A "Y" connector may be added to add a catheter for more than one delivery site.

When medication is injected into the injection port, it flows into the syringe, pushing the syringe plunger against the spring. As the syringe reservoir is filled, the spring produces more pressure on the plunger, providing pressure on the medication fluid. The medication then flows through the micro-glass cannula which controls the rate of flow (in a fail-safe manner). The fluid exits the system via the epidural catheter. Any break in the system will result in reduced or no drug delivery to the patient.

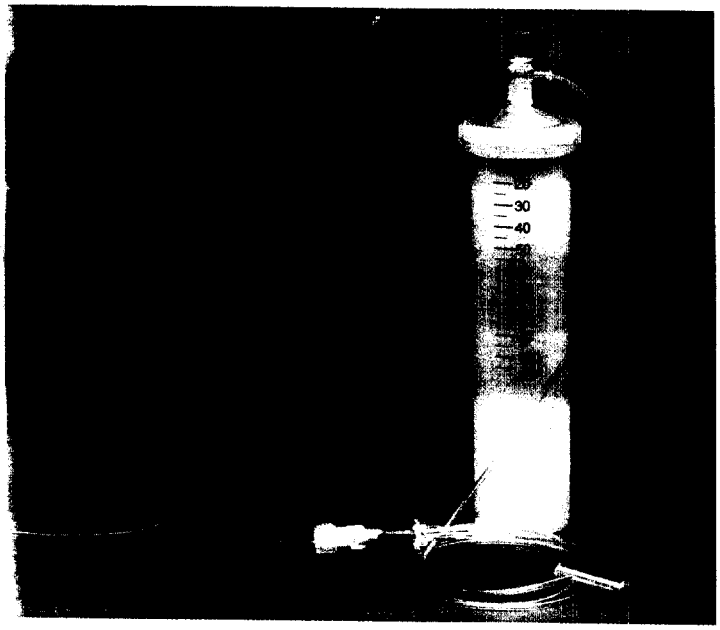
Clinical experience demonstrates that excruciating post-operative pain decreases over time in most patients. This observation is further demonstrated by the patient's diminishing need for narcotic analgesia to control pain. Continuous infusion of local anesthetic should provide analgesia and reduce the need for systemic medications with little risk to the patient.

A Significant Improvement in Portable Infusion

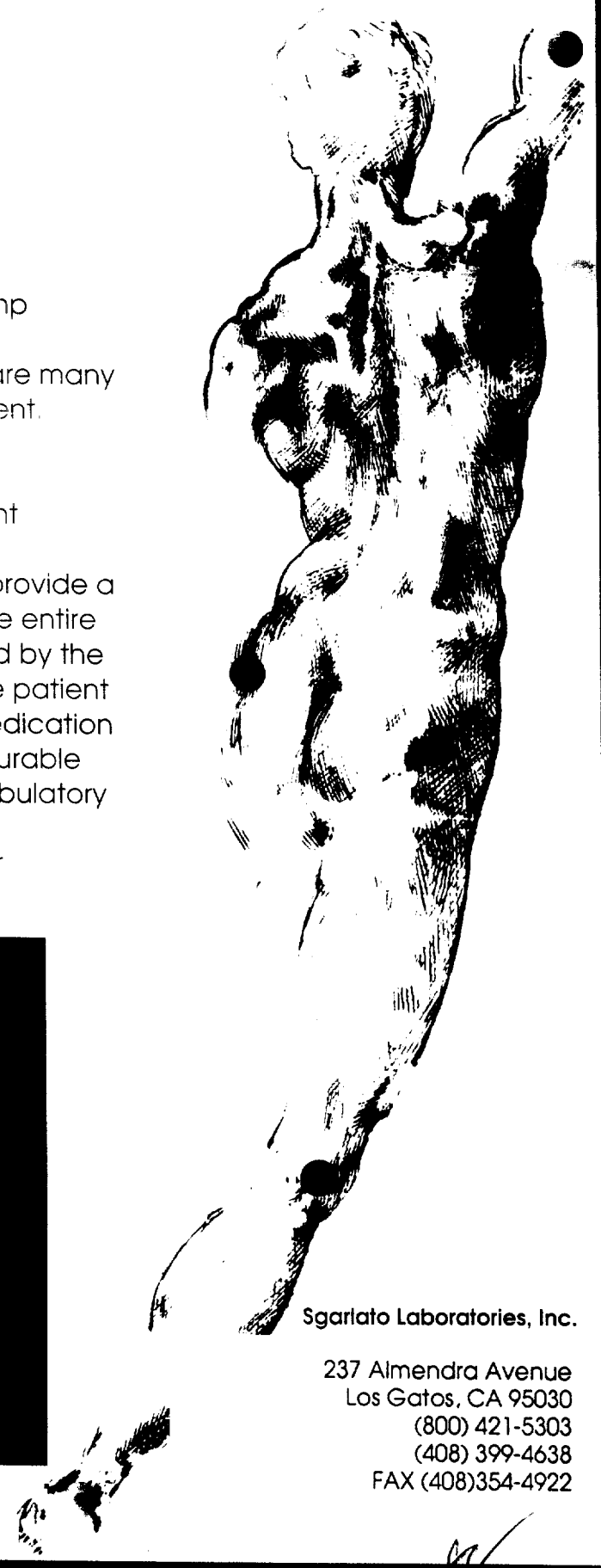
Take Aim at the Site of Pain

Now you can provide your patients with **safe, reliable, and accurate** continuous infusion via Sgarlato Lab's SurgiPEACE pump system. SP is suitable for delivery of local anesthetic directly to the pain site. There are many potential applications for pain management.

The SP system is a complete, lightweight disposable device which provides constant internal pressure via a unique precision compression spring and a flow resistor to provide a consistent infusion flow rate throughout the entire course of therapy. The flow rate is selected by the physician and cannot be changed by the patient thus ensuring safety and efficacy. The medication reservoir is constructed of a high quality durable and stable plastic which is suitable for ambulatory use. This simple and practical system is an excellent low cost option for many of your pain treatment needs.



Patent # 5,078,679 Patent # 4,997,420



Sgarlato Laboratories, Inc.

237 Almendra Avenue
Los Gatos, CA 95030
(800) 421-5303
(408) 399-4638
FAX (408)354-4922

Safe and Accurate

- Consistent and reliable flow rate throughout therapy via a precision compression spring.
- Tamper resistant design and unique flow restrictor prevent excess drug delivery and rate manipulation.
- Sterile "closed" system design with integrated tubing reduces risk of contamination.
- Disposable after single use.

Simple and Practical

- Drop counting, rate setting or electronic pump programming not required.
- Minimal patient and staff training.
- No cords, outlets, batteries or I.V. poles needed.
- Lightweight and compact design encourages patient compliance.

Flexible

Currently there are three flow rates available.

Model #	Flow Rate	Max Volume	Infusion Time
SP500	0.5 ml/hr	100 ml	8 days
SP1000	1 ml/hr	100 ml	4 days
SP2000	2 ml/hr	100 ml	2 days

Reliable and Durable

- Outer markings on barrel show exactly how much fluid is in the reservoir at any point in time.
- Durable hard plastic pump design minimizes possibility of pump being damaged or crushed, especially for long term use.
- All polypropylene housing provides for greater drug stability and less sensitivities compared to elastomeric pumps. Drug stability information is available.

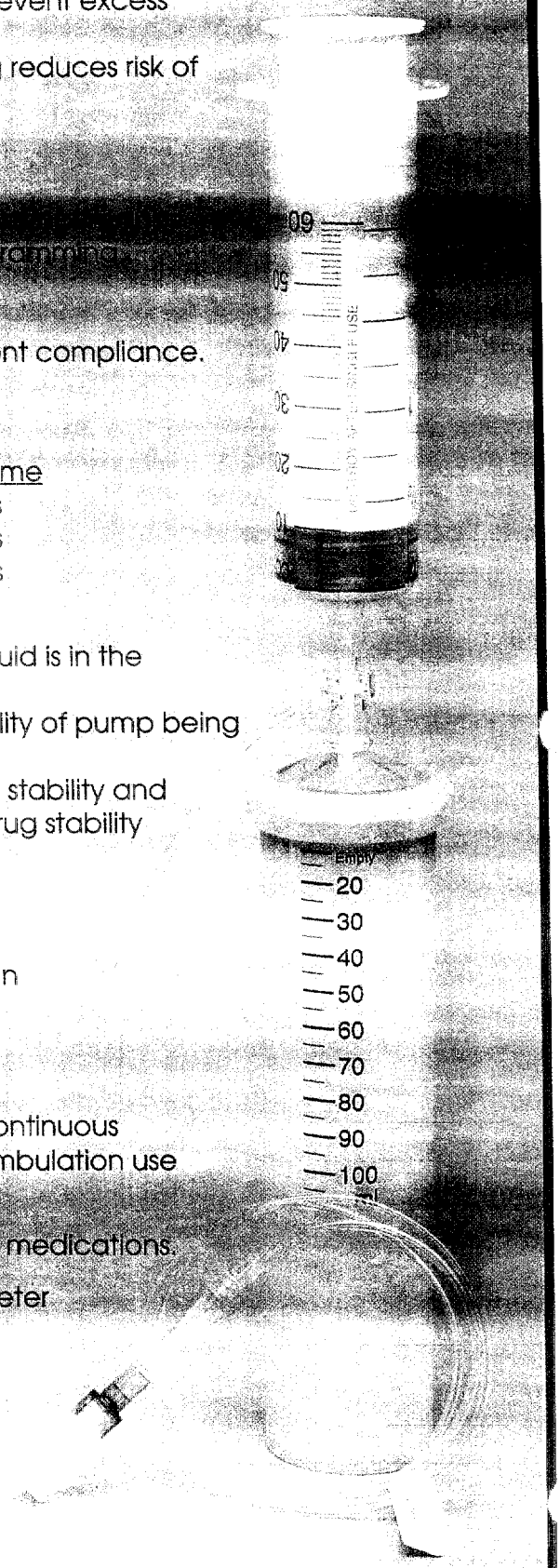
Cost Effective

- Low Cost
- Reduces or eliminates potentially expensive clinician intervention time.
- Low cost alternative to other more costly forms of pain treatment.

Indications and Usage: For patients requiring slow continuous administration of medication. It is convenient for ambulation use for inpatients, outpatients or home care.

Contraindications: Not designed for rapid infusion of medications.

Kit Options: Carrying harness, catheter, needle, catheter connector, "Y" adapter for multiple catheters.



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Homepump C-Series Predicate Labeling

The following contents are example labeling from the Homepump C-Series 65ml Volume, 0.5 ml/hr flow rate model:

- P/N 111111 - Directions for Use
- P/N 1301712 - Flow Rate Label
- P/N 111112 - Pouch Insert
- P/N 1301758 - Pouch Label
- P/N 1301757 - Inner Box Label
- P/N 1301759 - Shipper Box Label

HOMEPUMP®

DISPOSABLE ELASTOMERIC INFUSION SYSTEM

DIRECTIONS FOR USE

C-SERIES MODELS: C060020, C065005, C100020, C125050, C270010, C270020, C270100

The Homepump Disposable Elastomeric Infusion System is designed for use by ambulatory patients.

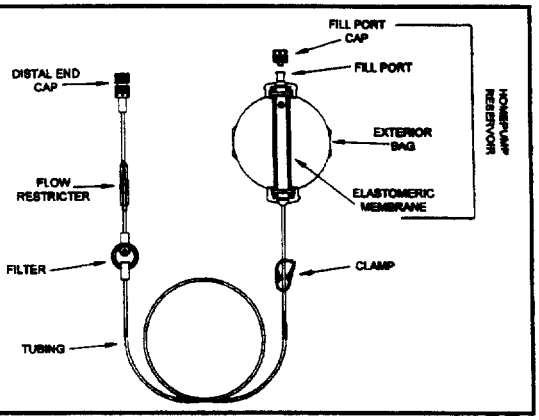
- The Homepump is indicated for continuous delivery of medications through intravenous, intra-arterial, subcutaneous or epidural routes.
- The Homepump is not intended for the delivery of blood, blood products or TPN.
- The Homepump tubing is made of DEHP plasticized PVC.
- **Epidural Administration:** Epidural infusion of analgesics is limited to use of indwelling catheters specifically designed for epidural delivery. To prevent infusion of drugs not indicated for epidural use, do not use IV set with additive ports. It is strongly recommended that devices used for administration of medication via epidural routes be clearly differentiated from all other infusion devices.

  Warning: Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.
- It is the responsibility of the pharmacist to assure, that the medication is prepared and administered in accordance with the drug manufacturer's package insert. It is the responsibility of the healthcare provider to assure the patient is educated on the proper use of this product.
- Refer to Center for Disease Control *Guideline for Prevention of Intravenous Therapy-related Infections* for specific recommendations regarding the usage of IV administration sets.

- Do not use while showering, bathing, or swimming.
- Do not microwave or submerge in water.
- Do not reuse.

Use aseptic technique.

1. Remove filled Homepump from protective plastic bag and verify that the clamp on the tubing is closed.
2. Remove distal end cap from tubing. Open clamp. Fluid will fill the tubing set. When all air has been expelled from the tubing set, close clamp.
3. Attach the Homepump tubing to the appropriate access site, as instructed by your healthcare provider.
4. Begin infusion by opening the clamp.
5. When the elastomeric membrane is no longer extended, infusion is complete; disconnect and dispose of the Homepump as instructed by your healthcare provider.



Effects of Environmental Factors (such as storage time, temperature, solution viscosity, backpressure, and/or fill volume) on Infusion Delivery Times

The information below will assist the healthcare provider in understanding these factors:

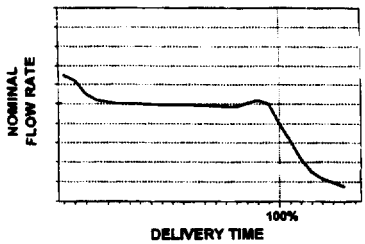
1. C-Series Homepump delivery should be started immediately after filling. Storage of a filled Homepump unit for more than 8 hours prior to starting infusion may result in a 10% longer delivery time.
2. If a filled Homepump unit needs to be stored in the refrigerator or freezer, for any reason, allow the unit to warm to room temperature before using: If refrigerated, allow 4 hours for C060020, C065005, C100020, C125050; allow 12 hours for C270010, C270020, C270100.
   If frozen, allow 8 hours for C060020, C065005, C100020, C125050; allow 24 hours for C270010, C270020, C270100.

   Note: Delivery time can increase significantly as a result of extended storage time.
3. The C-Series Homepump System is designed for the infusion tubing to be worn under the clothing, while the Homepump reservoir can be worn in the manner most comfortable to the patient. The Homepump flow restricter (located distal to the filter) should be close to, or in direct contact with, the skin (31°C/88°F).

   Temperature will affect solution viscosity, resulting in shorter or longer delivery time. If the Homepump is used with the flow restricter at room temperature (20°C/68°F), delivery time will increase by 25%.
4. Homepump delivery times are based on normal saline. Addition of any drug or use of another diluent may change viscosity and result in longer or shorter delivery time; use of D5W will result in a 10% longer delivery time.
5. When administering through a central intravenous, arterial, or epidural catheter, follow the instructions provided by the catheter manufacturer. The length, diameter, and position (pressure at catheter tip) may affect delivery time.
6. A Homepump filled with more than the nominal volume will infuse at a lower than nominal flow rate.

   A Homepump filled with less than the nominal volume will infuse at a higher than nominal flow rate.

Typical Flow Curve for a Homepump



Delivery Time Information for C-Series Homepumps

	C060020	C065005	C100020	C125050	C270010	C270020	C270100
NOMINAL FLOW RATE (ml/h)	2	0.5	2	5	1	2	10
NOMINAL VOLUME (ml)	60	65	100	125	270	270	270
MAXIMUM VOLUME (ml)	65	65	125	125	335	335	335
RETAINED VOLUME (ml)	2	2	3	3	8	8	8
APPROX. DELIVERY TIME	VOLUME (ml)						
6 h							60
12 h	38		35	75			160
18 h	42			100			200
24 h / 1 d	52		65	125			250
30 h	60						
48 h / 2 d			35	100			
60 h							
72 h / 3 d			45			175	
96 h / 4 d			55			215	
120 h / 5 d			65		155	260	
6 d					175	300	
7 d					195	320	
8 d					215		
9 d					230		
10 d					245		
11 d					265		
12 d					285		

A PRODUCT OF

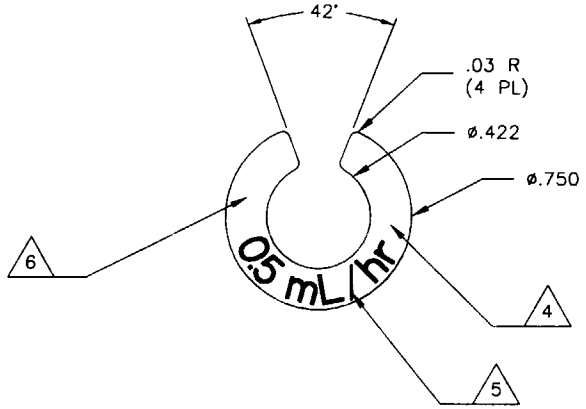
I-FLOW

I-FLOW CORPORATION
LAKEFOREST, CA 92630
USA

U.S. Pat. Nos. D324,911; 5,080,652; 5,105,983; and Foreign Pat. Pend.

111111B

REVISIONS			
REV	DESCRIPTION	DATE	APPROVED
A	PRODUCTION RELEASE PER DCO # 2803	5/27/97	RAV



CONTROL COPY

JAN 15 1998

MUST BE IN RED

6 COATING AP1010 UV VARNISH TO BE APPLIED POST LETTERING AND BACKGROUND COLOR.

5 LETTERING: 12.5 PT. ARIAL, COLOR: WHITE. TEXT CENTERED WITHIN THE LABEL.

4 BACKROUND COLOR: PMS 266c PURPLE.

3. MATERIAL: VINYL LABEL STOCK 3M7620 OR EQUIV, .0035 THICK.
2. USE ARTWORK SHOWN ON SHEET 3.
1. PART TO HAVE 3M TYPE 300 ADHESIVE OR EQUIVALENT, .001 THICK, WITH PAPER BACKING.

NOTES: UNLESS OTHERWISE SPECIFIED

MATERIAL: SEE NOTES		I-FLOW CORPORATION 10865 Rancho Bernardo Rd. CA 92127 (619) 618-2700	
FINISH:	APPROVALS / DATE	TITLE: FLOWRATE LABEL, SNAP CAP, 0.5 ml/hr	
UNLESS OTHERWISE NOTED ALL DIMENSIONS ARE IN: INCHES	CAD OPERATOR: 05/27/97		
TOLERANCES: LINEAR: .XX± .01 .XXX± .005 ANGLES: ± 0.5° CONCENTRICITY: ± FLATNESS: ± ROUNDNESS: ±	CHECKED: 5/27/97	SIZE: B	DRAWING NO.: 1301712 REV.: A
	APPROVED: 5/27/97		
DO NOT SCALE DRAWING		SCALE: 2:1	CAD FILENAME: 1301712A SHEET: 2 OF: 3

(4⅞")

HOMEPUMP®

DISPOSABLE ELASTOMERIC INFUSION SYSTEM

FOR SINGLE USE ONLY
- **Fluid pathway and areas under undisturbed protective caps are sterile and nonpyrogenic.**
- Do not remove from package until ready for use.
- Do not use if previously opened or damaged.
- See Directions for Use in the dispenser box.
- Storage: 10°-40°C, 10-90% relative humidity.

INFUSIONSGERÄT ZUR EINMALIGEN VERWENDUNG
- **Auf Sterilität und Pyrogenfreiheit geprüft.**
- Nicht verwenden, wenn Schutzkappen abgefallen oder gelockert sind oder wenn Packung beschädigt ist.
- Bitte Gebrauchsanweisung in der Sammelpackung beachten.
- Lagerung: 10°-40°C, 10-90% Luftfeuchtigkeit.

(6½")

DIFFUSEUR PORTABLE À USAGE UNIQUE
- **Stérile, apyrogène.**
- Vérifier l'intégrité du protecteur individuel avant usage.
- Se référer au mode d'emploi dans l'emballage de protection.
- Conserver à 10°-40°C, 10-90% humidité.

BOMBA DE INFUSION PARA UN SOLO USO
- **Estéril, apirógena.**
- No utilizar si el envase unitario no esta integro.
- Consultar el modo de empleo en la caja dispensadora.
- Conservar a 10°-40°C, 10-90% humedad.

STERILE EO

A PRODUCT OF

I-FLOW CORPORATION
LAKE FOREST, CA 92630
USA

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on order of a physician.

U.S. Pat. Nos. D324,911; 5,080,652; 5,105,983; and Foreign Pat. Pend.

Assembled in Mexico 111112, Rev. B

TITLE: C-Series pouch insert			
DRWG NO: 111112		REV: B	
SHT 3 OF 4		PRINTED AT 100 %	

96

(4 7/8")

DIRECTIONS FOR FILLING - Use Aseptic Technique.

1. Remove the cap from the fill port and retain for later use.
2. The HOMEPUMP can be filled with a syringe or other filling device. Remove all air from the filling device and attach it securely to the fill port.
3. Close the clamp and fill the HOMEPUMP with no more than the recommended maximum fill volume.
4. Remove filling device from the fill port.
5. Securely attach the cap to the fill port.
6. Label with the appropriate pharmaceutical and patient information.
7. Put HOMEPUMP into protective plastic bag for shipping and handling.

ANLEITUNG ZUM FÜLLEN - Auf aseptische Arbeitsweise achten.

1. Die Schutzkappe vom Füllport entfernen und zur Seite legen.
2. Die HOMEPUMP kann mit einer Spritze oder einer anderen Füllvorrichtung gefüllt werden. Die gesamte Luft aus der Füllvorrichtung entfernen. Füllvorrichtung sicher mit dem Füllport verbinden.
3. Die Klemme schliessen und die HOMEPUMP mit höchstens dem empfohlenen maximalen Füllvollumen füllen.
4. Die Füllvorrichtung vom Füllport entfernen.
5. Die Schutzkappe wieder aufsetzen.
6. Mit den entsprechenden pharmazeutischen und Patienteninformationen bezeichnen.
7. Für den Versand, Transport und kurzfristige Lagerung vorgesehene HOMEPUMP in den Kunststoff-Schutzbeutel verpacken.

(6 1/2")

INSTRUCTIONS POUR LE REMPLISSAGE - Utiliser une technique aseptique.

1. Retirer le bouchon protecteur du site de remplissage et le mettre de côté.
2. La HOMEPUMP peut être remplie avec une seringue ou un autre appareil de remplissage. Expulser tout l'air de l'appareil de remplissage et raccorder le de façon sûre au site de remplissage.
3. Fermer le clamp et remplir la HOMEPUMP sans dépasser le volume de remplissage maximum.
4. Retirer l'appareil de remplissage du site de remplissage.
5. Raccorder le bouchon protecteur sur le site de remplissage.
6. Etiqueter avec les renseignements pharmaceutiques et informations pour le patient appropriés.
7. Mettre la HOMEPUMP dans le sac protecteur en plastique pour l'expédition et la manutention.

INSTRUCCIONES PARA LLENAR - Use una técnica aséptica.

1. Remueva la tapa del orificio superior y reténgala.
2. El HOMEPUMP se puede llenar con una jeringa u otro sistema de llenado. Elimine todo el aire del sistema de llenado y conéctelo firmemente al orificio superior.
3. Cierre la pinza y llene el HOMEPUMP sin sobrepasar el máximo volumen recomendado.
4. Remueva el sistema de llenado del orificio superior.
5. Vuelva a conectar la tapa en el orificio superior asegurándola firmemente.
6. Márque el HOMEPUMP con la correspondiente información farmacéutica y del paciente.
7. Ponga el HOMEPUMP en la bolsa de plástico protectora para envío y manejo.

TITLE: C-Series pouch insert			
DRWG NO: 111112		REV: B	
SHT 4	OF 4	PRINTED AT 100	%

I-FLOW CORPORATION

Labeling Specification Form		Preparation Date: 02/04/98
☐ DFU (Direction for Use)	☒ Labels	☐ Other

Part Number: 1301758	Revision: B	Sheet: 1 of 1
Description: Label, Pouch, C-Series 65 ml Vol., 0.5 ml/hr		

Revision	DCO History	Release Date	Changed by	Checked by
A	Production release per DCO 2952	10/15/97	RF	LRH
B	Revised per DCO 3106	2/9/98	RF	SPN

1. Interpret dimension / tolerance in accordance with ANSI Y14.5M-1982.
2. Material: M/F 1301723
3. Text and artwork to be centered on applicable sheet size.
4. Text and artwork color: BLACK
5. Label background color: WHITE
6. Outside perimeter of label to have corners: ☒ radius, ☐ sharp.
7. ☐ Single sheet printed on both sides.
8. ☒ Single sheet printed on one side.
9. ☐ Standard size: 4.80" x 6.20" with 0.15" Border For Artwork.
10. ☒ Size: 3.75" X 5.5"
11. Refer to attached original artwork for text details.

CONTROL COPY

FEB 0 9 1998

MUST BE IN RED

Notes: 1. Items with check mark in box are applicable (refers to items 6 through 10 above).
2. QC to add the following to kit issued labels: Lot Number and Expiration Date.

Approvals: Final Artwork

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98

PRODUCT OF / EINE PRODUKT VON / UN PRODUIT DE / UN PRODUCTO DE

I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

CONTENTS / INHALT / CONTENU / CONTENIDO: 1

REF C065005
PART NO. 5001013

Homepump ECLIPSE® C-Series 65 ml Volume, 0.5 ml/hr

Assembled in Mexico

STERILE EO

LOT

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
SEE DIRECTIONS FOR USE.

Manufactured by / Hersteller von / Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

CE 0123

European Representative / Europaische Vertretung / Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

1301758B

I-FLOW CORPORATION

Labeling Specification Form		Preparation Date: 08/06/97
☐ DFU (Direction for Use)	☒ Labels	☐ Other

Part Number: 1301757	Revision: A	Sheet: 1 of 1
Description: Label, Box, Inner, C-Series 65 ml Vol., 0.5 ml/hr		

Revision	DCO History	Release Date	Changed By	
A	Production release per DCO	10/15/97	RF	LRH

1. Interpret dimension / tolerance in accordance with ANSI Y14.5M-1982.
2. Material: M/F 1301724
3. Text and artwork to be centered on applicable sheet size.
4. Text and artwork color: BLACK
5. Label background color: WHITE
6. Outside perimeter of label to have corners: ☒ radius, ☐ sharp.
7. ☐ Single sheet printed on both sides.
8. ☒ Single sheet printed on one side.
9. ☐ Standard size: 4.80" x 6.20" with 0.15" Border For Artwork.
10. ☒ Size: 3.75" X 8.0"
11. Refer to attached original artwork for text details.

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Notes: 1. Items with check mark in box are applicable (refers to items 6 through 10 above).
2. QC to add the following to kit issued labels: Lot Number and Expiration Date.

Approvals: Final Artwork

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I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

CONTENTS / INHALT / CONTENU / CONTENIDO: 6

MODEL NO.: C065005

PART NO.: 5001013

Homepump ECLIPSE® C-Series
65 ml Volume, 0.5 ml/hr

Printed in U.S.A.

Assembled in Mexico




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1301757A

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Labeling Specification Form		Preparation Date: 02/04/98
☐ DFU (Direction for Use)	☒ Labels	☐ Other

Part Number: 1301759	Revision: B	Sheet: 1 of 1
Description: Label, Box, Shipper, C-Series 65ml Vol., 0.5ml/hr		

Revision	DCO History	Release Date	Change By	Checked By
A	Production release per DCO 2952	10/15/97	RF	LRH
B	Revised per DCO 3106	2/9/98	RF	SPN

1. Interpret dimension / tolerance in accordance with ANSI Y14.5M-1982.
2. Material: M/F 1301724
3. Text and artwork to be centered on applicable sheet size.
4. Text and artwork color: BLACK
5. Label background color: WHITE
6. Outside perimeter of label to have corners: ☒ radius, ☐ sharp.
7. ☐ Single sheet printed on both sides.
8. ☒ Single sheet printed on one side.
9. ☐ Standard size: 4.80" x 6.20" with 0.15" Border For Artwork.
10. ☒ Size: 3.75" X 8.0"
11. Refer to attached original artwork for text details.

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Approvals: Final Artwork

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CONTENTS / INHALT / CONTENU / CONTENIDO. 24

REF C065005

PART NO. 5001013

Homepump ECLIPSE® C-Series
65 ml Volume, 0.5 ml/hr

Assembled in Mexico

STERILE EO

LOT

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1301759B

Homepump Eclipse Predicate Labeling

The following contents are example labeling from the Homepump Eclipse 50ml Volume, 50 ml/hr flow rate model:

- P/N 111064 - Directions for Use
- P/N 1301713 - Flow Rate Label
- P/N 110876 - Pouch Lidstock Label
- P/N 1301758 - Pouch Label
- P/N 1301759 - Shipper Box Label

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(b)(4)

HOMEPUMP
ECLIPSE
DISPOSABLE ELASTOMERIC INFUSION SYSTEM

CONTENTS:
TWO UNITS.

MODEL NO:

LOT NO:

RATE
ml/hr

STERILE, NONPYROGENIC FLUID PATHWAY IF PROTECTIVE CAPS ARE IN PLACE.
DO NOT USE IF PACKAGE HAS BEEN PREVIOUSLY OPENED OR DAMAGED.

DIRECTIONS FOR USE

• Use Aseptic Technique. • Do not use while showering, bathing, or swimming. • Do not reuse.
• Do not microwave or submerge in water. • Do not use with blood, blood products or TPN infusions.

1. Allow Homepump Eclipse to warm to room temperature before using. (For guidelines, refer to the table on the reverse side.)
2. Verify that the clamp on the tubing is closed.
3. Remove the cap from the end of the tubing; if required, attach a needle and remove its cover.
4. Open tubing clamp. Fluid will begin to flow, filling the tubing set. When all air has been expelled from the tubing set, close tubing clamp.
5. Attach the Homepump Eclipse tubing to your venous access site, as instructed by your healthcare provider.
6. Begin infusion by opening the clamp; fluid delivery will start immediately. If tubing is partially kinked, massage tubing to promote flow.
7. When the elastomeric membrane is no longer extended, infusion is complete. Disconnect and dispose of the Homepump Eclipse as instructed by your healthcare provider.

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on order of a physician.

U.S. Pat. Nos. D324,911; 5,080,652; 5,105,983; 5,284,481; and Foreign Pat. Pend.

110876, Rev. C Pkg. Pat. 4,367,816 Assembled in Mexico

STERILE R

European Representative:
MPS Medical Product Service GmbH
Borngasse 20 35619 Braunfels, Germany

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I-FLOW CORPORATION
LAKE FOREST, CA 92630
USA

Infusion delivery times for Homepump Eclipse elastomeric infusion devices are influenced by environmental conditions. The information below is provided to assist the healthcare provider in understanding these factors.

1. The Homepump Eclipse should be filled a minimum of four hours prior to administration. If the Homepump Eclipse is used immediately after filling, the flow rate may increase by up to 20% of its nominal rate. Storage conditions other than the specified usage conditions will affect delivery time.
2. Each Homepump Eclipse is designed to be used at room temperature (68°F/20°C). Temperature will affect solution viscosity, resulting in increased or decreased flow rate. If the Homepump Eclipse or its tubing is at 78°F/25°C, the flow rate will increase approximately 14% above its nominal rate; at 60°F/15°C, the flow rate will decrease approximately 12% below its nominal rate.
   The Homepump Eclipse should be worn outside the clothing, in the nylon carrying pouch designed to conveniently conceal and carry the Homepump Eclipse.
3. The flow rate may be decreased by infusion of more viscous fluids. Use of D5W will decrease the flow rate by approximately 8%.
4. When administering through a central or peripheral catheter, follow the instructions provided by the catheter manufacturer. Peripherally inserted central catheter (PICC) lines smaller than 20 gauge x 56 mm will decrease flow rate. Flow may be affected by positional catheters and/or access.
5. After priming the tubing set of the Homepump Eclipse, ensure that the distal end cap is tightened securely to prevent fluid evaporation and occlusion of the flow control tubing.
6. The patient should be instructed to check for any tubing occlusion at clamp site. After opening the clamp, if tubing is partially kinked, squeeze tubing to facilitate flow.
7. Use extra care when handling frozen units.

NOMINAL FILL VOLUME (ml)	50	100	100
FLOW RATE (ml/hr)	50	100	200
MAXIMUM FILL VOLUME (ml)	65	125	125
RETAINED VOLUME (ml)	3	3	3
TIME TO REACH ROOM TEMPERATURE			
hours from refrigerator	6	6	6
hours from freezer	12	12	12
UNITS PER CASE	48	48	48
APPROX. DELIVERY TIME	FILL VOLUME (ml)		
15 min.		40	60
30 min.	28	65	100
40 min.			125
1 hr.	50	100	
1 hr. 15 min.	65	125	

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(714) 206-2700

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I-FLOW CORPORATION

Labeling Specification Form		Preparation Date: 8/12/97
☐ DFU (Direction for Use)	☒ Labels	☐ Other
Part Number: 1301746	Revision: A	Sheet: 1 of 2
Description: Label, Box HP Eclipse 50ml Vol., 50ml/hr		

Revision	DCO History	Released Date	Changed By	Checked By
A	Revised per DCO 2873	9/16/97	JSC	KS

1. Interpret dimension / tolerance in accordance with ANSI Y14.5M-1982.
2. Material: M/F 1301724
3. Text and artwork to be centered on applicable sheet size.
4. Text and artwork color: Black
5. Label background color: White
6. Outside perimeter of label to have corners: ☒ radius. ☐ sharp.
7. ☐ Single sheet printed on both sides.
8. ☒ Single sheet printed on one side.
9. ☐ Standard size: 4.80" x 6.20" with 0.15" Border For Artwork.
10. ☒ Size: 3.75" x 8.0"
11. Refer to attached original artwork for text details.

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Notes: 1. Items with check mark in box are applicable (refers to items 6 through 10 above).
2. QC to add the following to kit issued labels: Lot Number and Expiration Date

Approvals: Final Artwork

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CONTENTS / INHALT / CONTENU / CONTENIDO: 48

MODEL: E050500

PART NO.: 5000985

Homepump ECLIPSE®
50 ml Volume, 50 ml/hr

STERILE R

LOT

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I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

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MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

1301746A

Br. J. Anaesth. (1986), 58, 790–800

LOCAL ANAESTHETIC TECHNIQUES FOR PREVENTION OF POSTOPERATIVE PAIN

E. N. ARMITAGE

HISTORY

The potential benefits of local anaesthetic techniques in the postoperative period have long been recognized. In a review of early work, Simpson and Parkhouse (1961) pointed out that, in 1935, Capelle irrigated abdominal wounds with local anaesthetic injected through large, curved, hollow needles. These were inserted at the end of the operation and left in place in a manner similar to deep tension sutures. The method was apparently effective, but was not adopted widely because of fear of wound infection and delayed healing. Gerwig, Thompson and Blades (1951) used the same principle when they inserted polyethylene tubes deep to the anterior rectus sheath for wound irrigation, and they noted that patients so treated required only a quarter of the usual amount of morphine.

Gius (1940) described the use of paravertebral block with procaine for the treatment of post-operative atelectasis, and Cleland (1949) used "continuous" caudal and extradural analgesia for over 100 abdominal and ano–rectal cases. He claimed that this resulted in normal postoperative respiration and early, painless ambulation. Bonica (1953) used intermittent injections through an indwelling extradural catheter to produce segmental analgesia, and found that this gave complete pain relief and allowed effective ventilation and coughing. Dawkins (1956) preferred to give extradural lignocaine as an infusion. He found that this technique was capable of providing truly continuous analgesia, and pointed out that the use of the word "continuous" is a misnomer when applied to intermittent injections or top-ups of local anaesthetic.

These pioneer workers had demonstrated that local anaesthetics produce excellent postoperative analgesia, but they had also encountered the drawbacks. Infusion systems were open to the criticism that the extent of block might be difficult to control and that any sudden, unsuspected hypotension could be dangerous to a patient in the sitting position (Bonica, 1957). Regarding intermittent top-ups, Simpson and colleagues (1961) summarized the situation as follows: "The exacting nature of the technique, the necessity for scrupulous asepsis, and the large numbers of injections required, make continuous postoperative analgesia by means of intermittent, mid-thoracic extradural block unsuitable for routine use except where the special facilities of an intensive therapy unit are available."

These early observations provide guidelines for the "ideal" local anaesthetic technique for use in the postoperative period. It should be effective over the whole of the painful area, but its extent should not be difficult to control. It should not readily produce toxic effects and should not be unduly labour-intensive. Side effects should be minimal.

EXTRADURAL BLOCK

This is particularly useful because it can provide analgesia after surgery of the thorax, abdomen, pelvis and lower limb.

Factors affecting the catheter

Position. The catheter must be placed so that local anaesthetic solution injected through it produces analgesia at the site of operation. The mode of spread of solution depends on the method of administration. Injected solution emerges from the catheter under pressure and spreads equally up and down the extradural space. The catheter tip should therefore lie at the segment innervating the middle of the required area of analgesia. For upper abdominal operations, this should be between T6 and T8. An infused solution enters the extradural space under minimal pressure and its spread is

E. N. ARMITAGE, M.B., B.S., F.F.A.R.C.S., Brighton General Hospital, Brighton, W. Sussex.

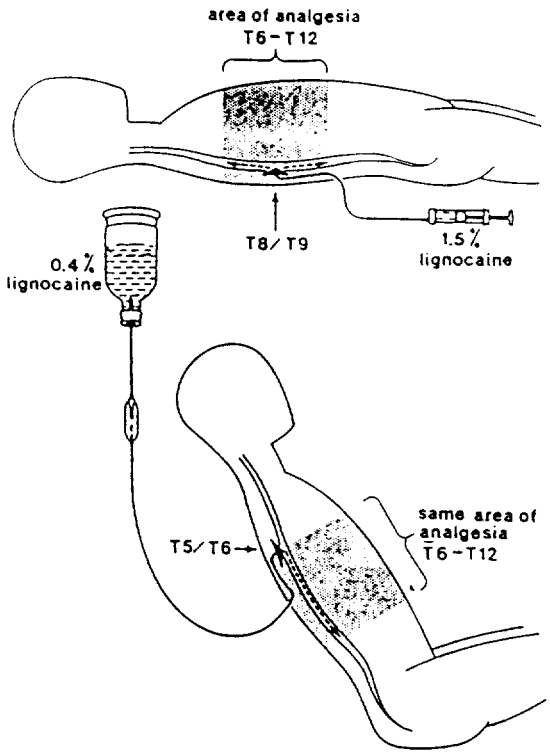

FIG. 1. The original illustration by Green and Dawkins (1966). The lower diagram shows the catheter tip placed at the upper end of the required area of block when the patient is in the 45° sitting position and the local anaesthetic is infused. The upper diagram shows the same area of analgesia obtained with the patient supine and the solution administered as a bolus.

mostly influenced by gravity. Since the patient is likely to be sitting up when the postoperative infusion is in progress, the catheter tip should be at the segmental level innervating the upper end of the surgical incision (fig. 1) (Green and Dawkins, 1966).

Insertion. When an extradural block is used only for the duration of surgery, it is customary to insert a short length of catheter (2–3 cm) to the extradural space. Looping and knotting cannot occur and the risk of venous and dural puncture is minimized. Although this is satisfactory during and immediately after the operation, the catheter tends to become extruded as the patient mobilizes and as infusions are continued or repeated injections given. At least 5 cm of catheter should therefore be inserted to the extradural space if long-term analgesia is planned.

Duration. The pain of major surgery is at its most severe and debilitating in the first 2 or 3 days and extradural analgesia is of most benefit during this time. Thereafter, the intensity of pain diminishes and it can usually be controlled adequately with i.m. opioids or oral preparations.

Infection is unlikely to occur when catheters are removed after 2 days and patients have been reported in whom they have been left in place for between 7 and 25 days (Dawkins, 1966; Lloyd and Rucklidge, 1969; Spoerel, Thomas and Gerula, 1970). However, skin infection was noted after 3 days at the entry site of the catheter in one instance. Infection of the extradural space is very rare (Baker et al., 1975), but it is serious when it occurs (Saady, 1976) and injections and infusions should be delivered through a system which includes a bacterial filter. Indwelling catheters can migrate and the tip can enter a blood vessel or puncture the dura. The length of time for which a catheter is left in place represents a compromise between these possible hazards and the benefits resulting from the analgesia. Two to three days would seem to be the optimal time.

Choice of drug

It is important that a local anaesthetic, given by intermittent bolus injection or by infusion, should not produce systemic toxicity. Reynolds (1971) found bupivacaine to have a wider safety margin than lignocaine or mepivacaine when given by intermittent injection during surgery. Tucker and Mather (1975) used a computer model to predict the pattern of drug concentrations in the extradural and plasma compartments, and concluded that longer-acting agents such as etidocaine accumulate rapidly in the extradural space, but slowly in the plasma (fig. 2). Systemic toxicity and tachyphylaxis were observed when lignocaine was administered as a continuous extradural infusion (Sjogren and Wright, 1972). Bromage (1975) found that, in low concentration, bupivacaine produced less motor block, for any given degree of sensory block, than did etidocaine, amethocaine and lignocaine. The evidence suggests that bupivacaine is the agent of choice for postoperative use.

It may be thought that the addition of adrenaline to the local anaesthetic could be beneficial on the grounds that the risk of systemic toxicity would be reduced, but in fact plasma concentrations are not significantly decreased (Wahba, Don and Craig, 1975). Hypotension is more marked when the local anaesthetic solution

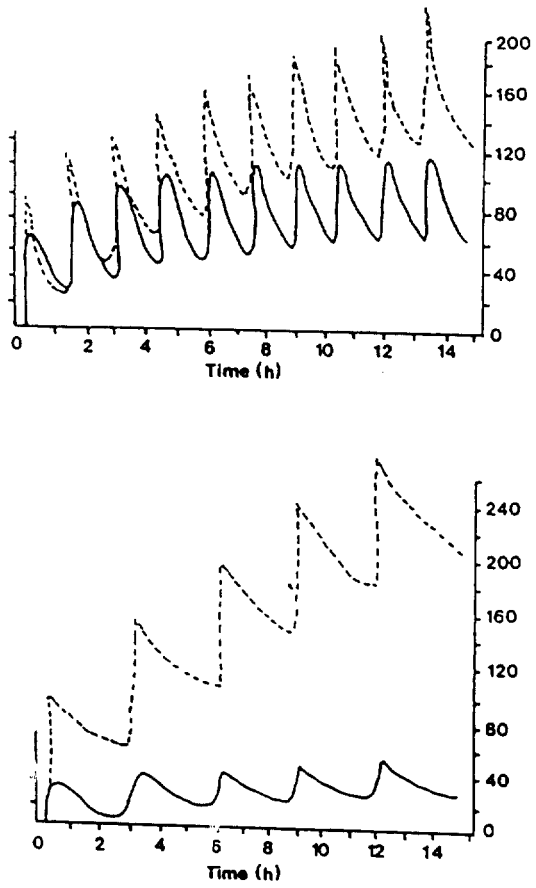

FIG. 2. Predicted local and systemic accumulation of lignocaine during multiple extradural injections at 1.5-h intervals (upper graph), and of etidocaine at 3-h intervals (lower graph). Continuous line: arterial plasma concentration. Broken line: amount unabsorbed (percentage of the initial dose). (From Tucker and Mather (1975).)

contains adrenaline (Kennedy, 1966) and in view of the possibility that the prolonged infusion of adrenaline might cause ischaemic nerve damage, its use should be avoided.

Anticoagulation

The extradural space is vascular and since the insertion of a catheter is a "blind" procedure, occasional damage to blood vessels is inevitable. Haemorrhage from such damage cannot be controlled directly and although this is of little clinical consequence in the presence of normal clotting mechanisms, it does have implications for patients receiving anticoagulants. Some will be receiving oral anticoagulants for pre-existing cardiovascular disease. Others may require heparinization during arterial procedures, and the administration of low-dose heparin for prophylaxis against deep vein thrombosis after major surgery is now widely practised.

There has been understandable reluctance to insert extradural catheters to patients in any of these categories, but there is evidence that the procedure may be safe in certain circumstances. Rao and El-Etr (1981) reported 3164 patients who received continuous extradural anaesthesia before the administration of heparin during operation. The activated clotting time was approximately twice the preoperative value, but the authors found no evidence of extradural haematoma. Odoom and Sih (1983) reported 950 patients who received intraoperative heparin after insertion of the catheter, but these patients had also received oral anticoagulants before operation and their clotting mechanisms were abnormal at the time of catheter insertion (mean thrombotest: 19%; normal range: 70–130%). None developed neurological complications.

Although these studies appear to demonstrate the relative safety of heparinization after insertion of an extradural catheter, the authors stress the importance of controlling the degree of heparinization through the activated clotting time, and they regard thrombocytopaenia, prior heparinization, long-term aspirin therapy and a thrombotest below 10% as contraindications. The management of the individual case depends on the balance between factors contributing to the thrombosis risk and the benefits likley to be conferred by the extradural. For major abdominal operations, the present author inserts the catheter before surgery and does not institute low-dose heparin therapy until 6–8 h after operation.

Bolus Injection

Intermittent injection, or topping-up, is the traditional method of prolonging analgesia into the postoperative period. It is satisfactory if the increments are given on a regular, timed basis with the objective of preventing pain. It is much less satisfactory if given on demand, since this implies that the presence of pain is the indication for a top-up. If the top-ups are to be given by nursing or medical staff, the patient nursed in an intensive therapy unit or a high dependency area stands a better chance of receiving prompt attention, and the method is therefore inappropriate for the majority of patients who return to a general

surgical ward. Early attempts were made to overcome this difficulty by the use of a mechanical injection device which delivered a predetermined dose of lignocaine or mepivacaine at regular intervals (Cox and Spoerel, 1964). More recently, Scott, Schweitzer and Thorn (1982) used a specially designed roller pump to deliver 6–10-ml doses of 0.5% bupivacaine 2 hourly. They found this provided good analgesia over 24 h. In the same study, another group of patients received 0.5% bupivacaine 4–5 ml given every 1–2 h by nurses. It was not possible to continue this regimen overnight and, even over the 8 h for which data were available, good analgesia was obtained in less than half the patients, because the nurses could not give the injections frequently enough. Schweitzer (personal communication) subsequently found that when 2-ml doses of 0.5% bupivacaine were delivered hourly through the pump, good analgesia was obtained.

Continuous Infusion

It was soon appreciated that it should be possible to maintain a constant state of analgesia by administering local anaesthetic by infusion. The method has the advantage that syringe drivers and variable rate infusion pumps are standard equipment and readily available, and the maintenance and monitoring is not labour-intensive.

Low volume/high concentration. Early workers (Spoerel, Thomas and Gerula, 1970) used standard concentrations of drug, 1 or 2% lignocaine or mepivacaine, at a rate of 5–12 ml h^{-1} after thoracic and abdominal surgery. They continued the infusion for an average of 3 days and claimed good results in 77% of cases. Pflug and colleagues (1974) achieved excellent analgesia after upper abdominal surgery, infusing 0.5% bupivacaine at a rate of 3–5 ml h^{-1}. They reduced the concentration to 0.25% on the 3rd day, but kept the rate constant. It would seem that further reduction of the rate results in variable blocks. This is because an infused solution, unlike a bolus injection, has minimal injection pressure to propel it away from the catheter tip, and an increase in drug concentration is insufficient to compensate for this lack of physical spread. Renck and colleagues (1976) gave 1% bupicavacaine at a rate of 0.75 ml h^{-1} after thoracic surgery and failed to achieve reliable analgesia.

High volume/low concentration. In the author's opinion, this is the method of choice. It involves the infusion of 0.1–0.125% bupivacaine 16–24 ml h^{-1}. Assuming that the catheter tip is appropriately placed, there is rarely any difficulty in achieving adequate spread of analgesia, motor block is less intense and drowsiness, a systemic side effect of bupivacaine, is less common than with the 0.25% solution (Griffiths, Diamond and Cameron, 1975). The accidental administration of excessive volume is likely to result in less severe toxic effects if a solution of low concentration is used. Hypotension is less common with an infusion than with a bolus technique (Scott, Schweitzer and Thorn, 1982), and infusions have been used safely on general surgical wards after abdominal and thoracic surgery (Ross, Clarke and Armitage, 1980). Unfortunately, local anaesthetics are not yet commercially available in low concentration and large volume, and suitable solutions have therefore to be specially prepared.

Practical aspects of management

Filters. Extradural filters are designed to prevent the passage of bacteria and are capable of excluding particles as small as 0.22 μm. When fluid is infused at a rate of, for example, 20 ml h^{-1}, particles accumulate rapidly on the filter and its resistance increases. The resulting increase in pressure between the filter and the pump may cause separation of the infusion line at a junction point. This problem can be overcome by changing the filter every 12 h, but it is the author's practice to insert a blood filter between the pack of local anaesthetic solution and the administration set. This removes the larger particles, and the bacterial filter usually lasts for the duration of the infusion.

The pump. Resistance in an infusion line is high, since fluid has to pass not only through the filter, but also along the narrow 90-cm long extradural catheter. The pump must therefore be powerful. It should also be quiet and accurate and give warning when solution is flowing faster or slower than the selected rate. Nursing staff should have easy access to an illustrated chart showing the common causes of, and remedies for, pump malfunction.

Bolus during an infusion. Although an infusion of 0.1% bupivacaine 20 ml h^{-1} will often give satisfactory analgesia for 2–3 days without the need for adjustment, the block will sometimes regress. Setting the pump at a higher rate will not correct a regressing block unless a bolus is first

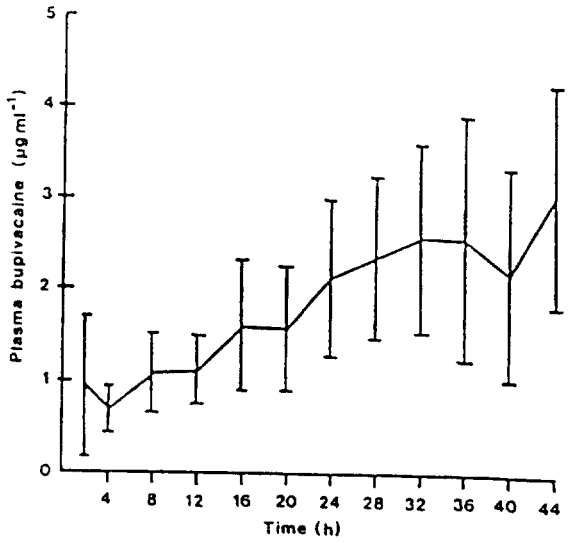

FIG. 3. Mean plasma bupivacaine concentrations (+SD) in nine patients kept free of pain with extradural infusions of 0.125% bupivacaine after abdominal or thoraco–abdominal surgery.

given to re-establish the required area of analgesia. A "bolus" can be given without breaching the infusion line by running the pump at 90 drops min^{-1}. A standard administration set delivers 4.5 ml during 1 min at this rate, and volumes of 4.5–9 ml are usually required. Griffiths, Diamond and Cameron (1975) infused 0.125% or 0.25% bupivacaine at 15 ml h^{-1} after thoracic surgery and achieved satisfactory analgesia in five of seven patients. However, in spite of this generous rate, a mean of five bolus doses (5–8 ml of 0.25% bupivacaine) was required during the 48-h period studied.

A regressing block may not be the only reason for a bolus being required. Gjessing and Tomlin (1979) have suggested that the intensity of postoperative pain is not constant, but cyclical. They identified four peaks (occurring at 4, 10, 14 and 18 h) during an 18-h period in women undergoing total hip replacement, and two peaks (at 6–8 and 12–16 h) in men having the same operation. They also suggested that patterns of pain may be different after different types of surgery.

Motor block. Weakness or paralysis of the lower limb muscles is not usually produced when nerves are subjected to intermittent bolus injections of local anaesthetic, but it is quite common, even with dilute solutions, during the course of an infusion. This is presumably because the large, resistant motor fibres eventually become affected after they have been bathed constantly for several hours. The patient should be warned of this possibility at the preoperative visit and assured that recovery of function occurs within 2 or 3 h after reduction of the infusion rate. Similarly, surgeons should be aware that symptoms do not necessarily betoken a neurological or vascular disaster.

Additional sedation. Since postoperative extradural block is performed to provide better pain control at the operation site than conventional opioid analgesia, it is sometimes felt that *any* discomfort indicates a failure of the block and that *no* opioid should be necessary. This attitude fails to take into account the fact that there are some sources of discomfort which the extradural is intrinsically incapable of relieving, or which lie outside its range. These include anxiety about the recent operation, sleeplessness as a result of noise and the need for frequent postoperative observations, and shoulder tip pain which is thought to result from pneumoperitoneum. The administration of occasional, small doses of opioid under these circumstances, far from devaluing the block, greatly enhances it and gives excellent overall results.

Plasma concentrations. The extradural infusion of a local anaesthetic drug over a long period may lead to potentially toxic plasma concentrations. Ross, Clarke and Armitage (1980) followed intraoperative boluses of 0.25% bupivacaine with the postoperative infusion of 0.125%, and measured venous plasma concentrations at 4-h intervals for 44 h. The infusion rate was adjusted so that patients were pain-free and side effects were minimal, and it varied between 12 and 36 ml h^{-1} with an average of 20 ml h^{-1}. This regimen produced mean venous bupivacaine concentrations of 3 μg ml^{-1} (range 1.3–4.9 μg ml^{-1}) after 44 h (fig. 3). Patients were assessed clinically when the blood samples were taken and no signs of cerebral toxicity were detected, although one patient became euphoric. Reynolds (1971) has stated that even mild toxic symptoms are unlikely to appear at plasma concentrations less than 1.6 μg ml^{-1}. Unfortunately, this figure has sometimes subsequently been taken to represent "the toxic level" for bupivacaine and this is

clearly an incorrect interpretation of the original statement.

The appearance of toxic symptoms depends on factors other than the plasma concentration. Scott (1975) administered i.v. bupivacaine at different rates to conscious volunteers and found that symptoms appeared at low plasma concentrations when the infusion rate was high. The rate of increase in concentration tends to be very slow when dilute bupivacaine is given by extradural infusion (fig. 3) and this may explain why no toxic effects were observed in Ross's patients. A further explanation may lie in the fact that α-globulin, the protein to which bupivacaine binds, increases after surgery and may match the increase in plasma bupivacaine concentration. The unbound fraction of the drug may remain virtually constant under these circumstances.

Although venous plasma concentrations are often measured, it is the arterial concentration which is more closely related to the development of toxic symptoms. Griffiths, Diamond and Cameron (1975) followed intraoperative injections of 0.5% bupivacaine (with adrenaline) 6–8 ml with a postoperative infusion of 0.125% bupivacaine at a mean rate of 13 ml h^{-1} and they supplemented this, as required, with boluses of 0.25% bupivacaine 5–8 ml. They took arterial samples and found a mean value of 2 μg ml^{-1} (range 0.93–3.76 μg ml^{-1}).

Effects on the cardiovascular system

Some degree of hypotension almost invariably accompanies extradural block and it is fear of its consequences and, perhaps, uncertainty about its significance which deters many from prolonging the block after operation.

The normal patient. The sympathetic denervation caused by extradural block results in peripheral arterial and venous dilatation. The latter gives rise to decreased venous return and, if the affected veins are below the level of the right atrium, cardiac output may be reduced. Mean arterial pressure decreases in proportion to the decrease in cardiac output and peripheral vascular resistance. As a consequence, coronary blood flow is reduced, but fortunately this is accompanied by a similar reduction in the myocardial oxygen requirement.

Sympathetic block below T4 results in dilatation of the splanchnic, pelvic and lower limb vessels, and various mechanisms come into play to compensate for this. Vasoconstriction above the level of the block occurs, mediated by unblocked sympathetic vasoconstrictor fibres (T1–4), and release of catecholamines may be mediated by any unblocked fibres to the adrenal medulla. Unblocked cardiac sympathetic fibres mediate an increase in myocardial contractility and heart rate. In addition, vascular tone below the level of the block may return because of autoregulation of flow by precapillary sphincters (Granger and Guyton, 1969) and it has been suggested that low plasma concentrations of local anaesthetic drug cause cardiovascular stimulation (Bonica, Berges and Morikawa, 1970).

Sympathetic block above T4 reduces or abolishes compensatory vasoconstriction in the head, neck and upper limb as well as the ability of the cardiac sympathetic fibres to stimulate the heart. It is therefore surprising that the cardiovascular changes noted with upper thoracic blocks have been relatively modest. McLean and colleagues (1967) found a 15–20% reduction in cardiac output and an increase in central venous pressure (CVP). Bonica and colleagues (1971, 1972) also demonstrated an increase in CVP and found that mean arterial pressure and peripheral resistance decreased by about 20%, but they observed no change in cardiac output or heart rate.

Relation of sympathetic to sensory block. There is disagreement as to whether or not a sympathetic block extends higher or lower than a somatic block. Bonica, Berges and Morikawa (1970) were unable to demonstrate any sympathetic block in two of eight patients, even though all had skin hypoalgesia. On the other hand, Horner's syndrome is occasionally seen following an extradural where the analgesia is confined to the lower thoracic segments. Wugmeister and Hehre (1967) concluded that sympathetic and somatic block extended to the same level because loss of pin prick and cold sensation affected the same area. The above evidence suggests that there is wide variation between patients. The practical consequence is that the incidence and severity of hypotension are also likely to vary.

Patients in pain. The effect of extradural block on the cardiovascular system of the postoperative patient was studied by Sjogren and Wright (1972). They maintained analgesia with 0.4% lignocaine infused overnight at a rate of 30–45 ml h^{-1} and took cardiovascular measurements before discontinuing the infusion. The measurements were repeated when the block had worn off and the

patients were in pain, and again when the infusion had been re-commenced and the patients were pain free. The measurements taken when patients were in pain showed an increase in cardiac output, heart rate and mean arterial pressure and a decrease in stroke volume and skin blood flow—changes which indicated a strong sympathetic stimulation of the circulation. Re-establishment of analgesia was followed by a return to the values obtained before pain had been allowed to occur. Holmdahl and colleagues (1972) gave continuous extradural analgesia after cholecystectomy and found that hypotension was less of a problem when the catheter was placed in the thoracic rather than the lumbar region.

Effects on the respiratory system

Patients who have undergone major thoracic and abdominal surgery are prone to respiratory infection because pain prevents them from breathing deeply and coughing effectively. The abolition of pain by continuous extradural block might be expected to improve pulmonary function, and various aspects of the subject have been investigated.

The normal patient. Extradural block has very little effect on respiratory parameters in the normal patient. A block to the level of T4 had no significant effect on functional residual capacity (FRC), expiratory reserve volume (ERV) or inspiratory capacity. However, a block extending higher than T4 caused a decrease in ERV of 12–36 % (Freund et al., 1967; Sjogren and Wright, 1972; Takasaki and Takahashi, 1980). Arterial blood-gas tensions showed little change (Ward et al., 1965). Extradural block should theoretically allow unopposed vagal tone to cause bronchoconstriction, but no such change was found, even in the presence of high blocks, in three separate studies (Sjogren and Wright, 1972; Wahba et al., 1972; Takasaki and Takahashi, 1980) and Bromage (1978) quoted patients in whom extradural block has actually proved therapeutic in status asthmaticus.

The ability to cough effectively requires co-ordinated, powerful contraction of the diaphragm and muscles of the abdominal wall. Motor block to the latter occurs during upper thoracic spinal anaesthesia (Egbert, Tamersoy and Deas, 1961), but extradural block has minimal effect, perhaps because motor block cannot be shown to extend as high as sensory block (Freund et al., 1967).

Patients in pain. The effects of extradural block are not as dramatic as might be expected. There is sometimes improvement in lung volume measurements such as FRC and vital capacity (VC), but results are inconsistent and improvement is limited to reduction of deterioration rather than restoration of preoperative values (Simpson et al., 1961; Wahba, Don and Craig, 1975). However, the greatest benefit is seen in patients with chronic obstructive airways disease after upper abdominal surgery. Extradural block improved the VC from 37 % of the preoperative value to 90 % in these patients (Simpson et al., 1961). The effect on arterial blood-gas tensions is even less impressive. Patients are relatively hypoxaemic on the 1st day after upper abdominal surgery, whether they have received extradural analgesia or not (Muneyuki et al., 1968; Spence, Smith and Harris, 1968; Sjogren and Wright, 1972; Pflug et al., 1974; Spence and Logan, 1975), and when pain is relieved by extradural block, no improvement in Pa_{O_2} is seen (Muneyuki et al., 1968; Drummond and Littlewood, 1977).

There is, however, a marked improvement in the ability to cough. Sjogren and Wright (1972) studied patients receiving thoracic and lumbar extradural analgesia after gall bladder surgery and found that the peak expiratory flow rate increased by 64 % and 90 %, although these improved values were still only approximately one-half those obtained before operation.

It is not easy to find clear-cut evidence that extradural block causes significant improvement in respiratory function or reduces the incidence of postoperative chest infection in normal patients. However, since extradural analgesia improves the ability to cough, and increases VC to a greater extent in patients with chronic obstructive airways disease, it probably conveys most benefit to this group of patients, who most need it.

Other effects

Lower limb blood flow. Extradural block increases blood flow to the lower limb (Bonica, Berges and Morikawa, 1970), the skin receiving most of the increase (Cousins and Wright, 1971). Therefore flow must increase through the long and short saphenous veins, which drain the skin, and also through the femoral and iliac veins. Since thrombi in the latter vessels are most likely to result in pulmonary embolism (PE) (Modig et al., 1983), extradural block may be expected to play an

important part in the prevention of deep vein thrombosis (DVT) and PE.

Total hip replacement carries a high incidence of DVT, and PE is the commonest cause of immediate postoperative death after this procedure. Modig and colleagues (1983) studied patients in two groups, one of which received extradural anaesthesia for the operation and extradural analgesia after operation, and the other in which general anaesthesia was followed by postoperative opioid analgesia. The incidence of DVT was reduced significantly in the extradural patients. Lung scans were used to detect PE, which was found in 33% of the general anaesthesia/opioid group, but in only 10% of the extradural group.

Gastric emptying and intestinal motility. Opioids delay gastric emptying and reduce intestinal motility (Nimmo et al., 1978). Extradural block, by eliminating or greatly reducing the need for opioids, avoids these problems, but it also has a direct effect on the bowel, mediated by the sympathetic system. Increased sympathetic activity inhibits bowel contractility and predisposes to distension. This in turn increases tension, and hence the likelihood of rupture, at sites of anastomosis. Extradural block, by reducing sympathetic activity, reverses these trends; paralytic ileus is minimized and the nasogastric tube, which contributes to inefficient coughing and expectoration, can be removed early. Peristalsis is sometimes very active and diarrhoea occasionally persists into the postoperative period. The author has in one instance had to discontinue an infusion for this reason. However, the overall benefits are considerable (Aitkenhead, 1984).

Monitoring

It is important, whether the patient is nursed in an intensive therapy unit, a high-dependency area or a general ward, that the nursing and medical staff are familiar with the behaviour and management of patients receiving extradural analgesia, and the ways in which they differ from those receiving opioids. Systolic arterial pressure remains low for the first 12–24 h, but usually increases without specific therapy on the 1st day after operation. Ephedrine is occasionally required. Fears that the relative hypotension and complete analgesia may mask abdominal signs, causing delay in diagnosis of surgical complications, are groundless. Patients suffering from haemorrhage or an anastomotic leak look and feel unwell, in marked contrast to those running a normal postoperative course with extradural analgesia.

It is possible to check the infusion rate and the integrity of the line without disturbing the patient, and this should be done hourly. The adequacy of the block should be assessed every 4 h during the day. The patient should not only be free from pain at rest, but should be able to lift his head off the pillow from the 45° sitting position, take a deep breath, and cough, without pain. If any of these tests cause discomfort, a bolus should be given and the tests repeated after 15 min. The patient should be able to move both lower limbs. If a patient has a stable and easily controlled block, it is unnecessary to disturb him for assessments during the night. However, an early assessment is essential the following morning so that any adjustments can be effective before the arrival of the physiotherapist.

OTHER BLOCKS

It is not always necessary or desirable for a block to extend over a wide area, involve the sympathetic system or act bilaterally. Many blocks are capable of providing excellent analgesia, with minimal systemic effect, over a limited field, but although they have been used satisfactorily as single-shot techniques, they have not gained widespread acceptance for prolonged postoperative analgesia because it has been assumed that they must be repeated every few hours. This assumption is not necessarily correct, because it has been found that a catheter can be inserted through the fascial sheaths which surround neurovascular compartments. The sheaths extend peripherally and invest individual nerves, and Winnie, Ramamurthy and Durrani (1973) have shown that local anaesthetic solution injected through the sheath of, for example, the femoral nerve can be made to track centrally in the neurovascular compartment so that it affects the obturator nerve and lateral cutaneous nerve of the thigh in addition.

Paravertebral

Eason and Wyatt (1979) used continuous paravertebral block for analgesia after thoracotomy. They located the paravertebral space by loss of resistance to injection of air, and passed an end-hole extradural catheter into the space through a Tuohy needle. They found that at least four segments were affected by a single, 15-ml injection of 0.375% bupivacaine. The advantages

claimed for the technique are that it can be performed comparatively easily in patients with kyphoscoliosis and other distortions of the bony spine, and hypotension is minimal since sympathetic block is unilateral.

Intercostal

Murphy (1983) inserted an extradural catheter through a Tuohy needle to an intercostal space in 25 patients who had undergone cholecystectomy through a Kocher incision. Only two patients required any supplementary opioid on the 1st day after operation, but on the 2nd this figure had increased to six. Peak flow measurements were made on the 2nd day before and after an injection of bupivacaine. A mean improvement of 37% was recorded 30–40 min after the top-up.

Inguinal paravascular (three-in-one)

Rosenblatt (1980) used this technique for postoperative analgesia after knee surgery in a 13-yr-old patient suffering from cystic fibrosis. An 18-gauge, 5-cm Teflon catheter was threaded over a 22-gauge, 8.75-cm spinal needle. When the needle had entered the fascial sheath surrounding the femoral nerve, local anaesthetic was injected to distend the sheath and facilitate passage of the catheter. On the 1st day after operation, 0.75% bupivacaine 15 ml was injected every 6 h. On the 2nd day, 0.5% bupivacaine was infused at 4 ml h^{-1} and continued for 24 h.

Sciatic

Smith, Fischer and Scott (1984) described a technique for continuous sciatic nerve block which they used first to relieve the pain of an ischaemic foot and later, with an inguinal paravascular block, for postoperative analgesia following below-knee amputation. They located the sciatic nerve with a 16-gauge Medicut cannula connected to a nerve stimulator. After the injection of 2% lignocaine 8 ml to open up the neurovascular space, a 16-gauge extradural catheter was passed easily into it. Bupivacaine 0.5% was infused at a rate of 6 ml h^{-1} through both the femoral and sciatic catheters for 48 h, and the patient was completely free of pain.

Axillary

Although the brachial plexus can be blocked at various points along its course, the axillary approach is the most suitable for insertion of a cannula. A 20- or 22-gauge i.v. cannula is recommended and it is less likely to be dislodged during an injection if an extension set is interposed between it and the syringe or pump (Hughes and Desgrand, 1986). Rosenblatt, Pepitone-Rockwell and McKillop (1979) performed an axillary block for the repair of injured tendons in the hand of a 15-yr-old boy. They infused 0.25% bupivacaine at a rate of 10 ml h^{-1} for 2 days and the patient required no narcotic agents. Rosenblatt recommends that cannulae should be sutured in position if they are to be used for postoperative analgesia. The application of an occlusive, transparent, adhesive drape probably immobilizes the cannula just as well and has the advantage that the puncture site and surrounding skin can be inspected easily for signs of infection.

CONCLUSION

"Slapping the patient on the face and telling him or her that 'it's all over' is a complete inversion of the truth. As far as the patient is concerned, it is just the beginning" (Berry, 1979).

There is irrefutable evidence that patients suffer considerable pain after operation (Donald, 1976; Foott, 1978). Suitable drugs, equipment and techniques are available. The problem is essentially the practical one of how to provide analgesia safely, simply and continuously for 2–3 days. The solution depends as much on organization and attitudes as on techniques. One reason for the inadequacy of conventional opioid analgesia is that it is prescribed by members of one profession and administered by members of another. The result is that neither doctors nor nurses take full responsibility for it. Analgesia should be the responsibility of a small number of designated individuals and its effectiveness should be their main concern. A second, related, requirement is that the experience and availability of staff must be taken into account when the method of local anaesthesia is being selected, so that it can be easily and safely managed. This factor may determine whether analgesia is best administered by intermittent injections or by infusion. Last, there is little prospect of patients enjoying complete, continuous analgesia as long as their attendant staff think and talk in terms of pain relief. Analgesia should be given with the intention of preventing pain rather than relieving it.

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Continuous infusion techniques for postoperative pain relief

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Recently, there has been a major increase in the use of regional anaesthesia as part of a balanced anaesthetic technique. The subsequent utilization of continuous conduction blockade is now frequently used to provide analgesia in the postoperative period. The treatment of pain after surgery is central to postoperative care, but vigilance is required to ensure safety.

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Introduction

The safe provision of continuous neural blockade as part of a postoperative analgesic regimen depends on sound principles of patient management. Continuous infusion techniques supplying local anaesthetic, opioid, or other additives to peripheral nerves or the central neuraxis, demand a high level of supervision to avoid patient morbidity or mortality. The treatment or prevention of pain, in itself, is a humanitarian gesture but the question of whether pain is harmful remains unanswered. Some have argued that the abolition of the 'surgical stress response' reduces surgical morbidity [1], but are we simply substituting one risk for another?

Site of the catheter

The continuous infusion of a local anaesthetic or mixture of drugs requires the placement of a catheter at a site at which the drugs can have an effect. Local anaesthetics must be deposited accurately at the proposed site of action but opioids or adrenergic drugs can diffuse to exert an effect in the spinal cord or brain. The following sites of catheter placement have been used in recent years: epidural, subarachnoid, paravertebral, intercostal, interpleural, brachial plexus, and lower limb (femoral, sciatic, psoas compartment).

These techniques of conduction blockade have recently been reviewed by McClure and Wildsmith [2]. The vast majority of papers in the recent review period have been restricted to the technique of continuous epidural infusion and this review therefore reflects this. The paucity of research into the other techniques is indicative of their lack of popularity in clinical practice. The technique of continuous interpleural block was briefly fashionable, but as laparoscopic cholecystectomy has replaced open cholecystectomy in surgical practice, this analgesic technique appears to be looking for a new surgical indication.

Site of the epidural catheter

There are currently a number of published studies comparing local anaesthetics, opioids and clonidine in various concentrations and in a variety of mixtures. Some papers reach conclusions which, though valid for the strict conditions of a controlled trial, must not be inappropriately extrapolated to clinical practice. A recent study by Badner and Komar [3] is such an example. Patients were studied undergoing elective abdominal or thoracic surgery and the epidural catheters were sited at T11 12 or below. One could argue that it is not surprising that local anaesthetic administered at this level by slow infusion had no effect, as it was not administered close to the nerves which should have been blocked postoperatively. It may be that the siting of an epidural catheter is not so crucial when comparing opioid- or clonidine-containing mixtures, but the more fat-soluble agents may require administration close to the spinal cord itself to ensure an effect and to avoid sequestration in the fat in the lumbar epidural space.

Drugs

Many drugs have been used by continuous epidural infusion, singly or in combination, for postoperative analgesia. At present, practical and effective analgesia is commonly achieved with a combination of drugs in an attempt to reduce the side effects. Most recent studies have endeavoured to achieve the optimal 'recipe' of infusion mixture after a variety of surgical procedures. Efficacy has usually been assessed by comparing 'pain scores' at rest, on coughing or during mobilization, and recording the

Abbreviations

CEIA—continuous epidural infusion analgesia; PCEA—patient-controlled epidural analgesia.

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incidence of side effects. Occasionally, sensory and motor blockade are measured. It is generally impossible to directly compare one study with another owing to variations in study design.

Local anaesthetic and opioid

Dahl *et al.* [4•] have compared patients undergoing major abdominal surgery with thoracic epidurals placed between T9 and T12. One group received epidural morphine alone at 0.2 mg/h and the other received the same dose of morphine plus bupivacaine at 10 mg/h. In addition, both groups received non-steroidal anti-inflammatory drugs. The group which received bupivacaine and morphine had lower pain scores on coughing and mobilization, but no difference was seen between the groups at rest. The authors emphasized that pain requires assessment during coughing and mobilization.

Coppe and Willaert [5] also studied patients undergoing major abdominal surgery, this time with thoracic epidurals placed at T7–8. The authors used higher doses, giving bupivacaine 20 mg/h to each group. In addition, one group received sufentanil 5 μg/h and the other group received morphine 0.5 mg/h. The sufentanil group had a loading dose of 8 ml 0.5% bupivacaine and 50 μg sufentanil, whereas the morphine group had a loading dose of 8 ml 0.5% bupivacaine alone. Both regimens provided excellent analgesia, but the incidence of respiratory depression was much higher in the sufentanil group (33%) than in the morphine group (4%). Respiratory depression was early and was defined as requiring ventilation for a period of greater than 30 min postoperatively, despite complete reversal of muscle relaxation. Arterial hypotension was also seen in both groups after the loading dose. The authors recommend a lower dose of sufentanil and bupivacaine.

A well designed study of patients undergoing abdominal aortic surgery was carried out by George *et al.* [6••] to determine which type of thoracic epidural infusion provided the best postoperative pain relief. The authors compared 0.2% bupivacaine alone, fentanyl 10 μg ml alone, or a mixture of the two. Each drug was given by a 5 ml bolus postoperatively in the intensive care unit and then infused at a rate of 5 ml/h. Further analgesia, if required, was provided by morphine given by patient-controlled apparatus. Pain relief, pulmonary function, cardiovascular stability and side effects were assessed. Pain relief was excellent in the 'mixture' group; significantly better than the other two groups. The incidence of side effects was low. Pruritus occurred exclusively in the fentanyl groups and lower limb weakness in the bupivacaine groups.

Side effects during continuous epidural infusions are not uncommon. Motor block is undesirable in the postoperative period as it may predispose to pressure sores or deep venous thrombosis. Patients are also anxious if they experience any paralysis of the lower limbs.

The side effects of continuous epidural morphine have been compared with those of fentanyl in a recent study by White *et al.* [7•]. The patients received lumbar epidurals for total hip or knee replacement and were randomly allocated to receive a bolus dose of morphine (mean 3.9 mg) or fentanyl (mean 85 μg) followed by an infusion of morphine (mean 427 μg/h) or fentanyl (mean 56 μg/h). Respiratory effects were assessed by arterial blood gases and respiratory rate. Nausea, somnolence and pruritus were assessed by visual analogue scores. Pain relief was good and was similar in both groups. In the morphine group, partial pressure of CO_2 in arterial blood was elevated and nausea occurred over a period of more than 12 h. In the fentanyl group there was no change in partial pressure of CO_2 in arterial blood and nausea was confined to the first few hours. Somnolence was common in both groups. Pruritus was generalized in the morphine group and segmental in nature in the fentanyl group. All patients were catheterized and therefore urinary retention was not assessed. This particular side effect is often cited as a major disadvantage of both epidural local anaesthetic and opioid administration because of the perceived risk of bacteraemia as a result of urinary catheterization before or after prosthetic orthopaedic surgery.

Clonidine

The risk of respiratory depression secondary to epidural opioids has led various workers to investigate the use of alternative analgesics. Carabine *et al.* [8] have examined the effectiveness of epidural clonidine infusions for postoperative analgesia and the effect of clonidine on epidural morphine after total hip replacement. Patients were randomly allocated to receive one of two doses of epidural clonidine, 25 μg/h or 50 μg/h; low-dose morphine 0.1 mg/h; or a combination of morphine and clonidine. The patients also received a loading dose of clonidine 150 μg or morphine 1 mg, or a combination of the two. Pain scores in the morphine group were significantly greater than in the clonidine groups and the combination group in the first hour after surgery, presumably reflecting the slow onset of this low dose of morphine. The requirements for systemic analgesia were lower in the combination and larger dose clonidine group. Arterial pressure was reduced in the clonidine groups although the incidence of clinical hypotension was low. There were no significant differences between the groups in emetic symptoms (19% overall) or urinary retention (12% overall).

Mogensen *et al.* [9] also found that administering epidural clonidine 75 μg bolus, then 18.75 μg/h, added to low-dose epidural bupivacaine and morphine, gave enhanced analgesia during coughing and mobilization. Clonidine is

a complex drug with analgesic properties thought to be due to an effect at α_2 adrenoreceptors in the spinal cord.

Patient-controlled epidural analgesia

A study by Owen *et al.* [10] in patients who had undergone elective abdominal surgery has shown that patient-controlled epidural analgesia (PCEA) gives as good analgesia, with reduced dosage, when compared with continuous epidural infusion analgesia (CEIA) with fentanyl. PCEA fentanyl; 25 µg bolus, 15 min lock-out was compared with CEIA fentanyl, 50 µg/h. The patients in the PCEA group also showed less oxyhaemoglobin desaturation as assessed by continuous pulse oximetry. Nolan *et al.* [11] in a similar study, using a mixture of 0.125% bupivacaine and 1 µg/ml fentanyl after post-traumatic pelvic reconstruction, found no difference in pain relief or dosage requirements between a PCEA group and a CEIA group. The PCEA group, however, also received a small background infusion of the mixture.

Complications

Respiratory depression is now a well recognized and feared complication of epidural opioids. The risk is either attributed to systemic absorption or to rostral spread of opioid in the cerebrospinal fluid. Respiratory depression has been most commonly reported after bolus subarachnoid or bolus epidural administration of a water-soluble drug, such as morphine, which remains within the cerebrospinal fluid and then spreads rostrally.

Epidural catheters have been known to migrate to the subarachnoid space possibly because the presumed epidural placement was in fact subdural and the catheter gradually erodes the arachnoid matter. The risk of an epidural infusion becoming subarachnoid is ever present and some 'marker' should be introduced to allow such an event to be detected. If opioid alone is used and is administered accidentally into the subarachnoid space, the only indication will be gradual or sudden respiratory depression. A recent open study by Morton *et al.* [12] observed the effect of subarachnoid administration of 0.125% bupivacaine at 15 ml/h. The study showed that a developing lower limb motor block, or sensory block of the sacral roots, is a reliable sign of subarachnoid infusion. It is a common misconception that a rising upper sensory level will be apparent, but this was not a reliable sign. The use of local anaesthetic as 'a marker' to indicate inadvertent subarachnoid infusion may increase the safety of epidural opioid administration.

Madej *et al.* [13••] compared hypoxaemia and pain relief after lower abdominal surgery in patients given either an epidural infusion of bupivacaine and diamorphine or patient-controlled intravenous diamorphine analgesia. The authors found the lowest pain scores in the epidural infusion group but these patients were moderately hypoxaemic. The patient-controlled intravenous diamorphine analgesia group had a high incidence of emetic sequelae (90%) in the absence of parenteral antiemetic therapy but nevertheless were very satisfied with their analgesia. These workers make the very pertinent point of the high level of nursing care required for patients with epidural infusions. Rather than offer the technique to all in normal clinical practice, they now restrict it to specific medical indications and complex surgery.

Conclusion

There is no doubt that excellent postoperative analgesia can be obtained by continuous epidural infusion of analgesic drugs. The optimal 'recipe' for all surgical situations currently eludes us. The benefit is, however, bought at a price in terms of patient safety. These techniques demand extra vigilance, resource and commitment. We are now beginning to see good comparisons of different analgesic strategies. It is hoped that the sophisticated analgesic techniques will be reserved for those in most need of them, in a safe postoperative environment.

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Review Articles

Wound infiltration with local anaesthetics for postoperative pain relief

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In recent years there has been increasing interest in peripheral mechanisms of nociception and the afferent nerve terminal and its surroundings as a possible target for analgesics and modification of the response to surgical injury (1–3). Systemic administration of non-steroidal antiinflammatory drugs (NSAID), due to modulation of the arachidonic acid cascade, have been demonstrated to be of value as adjuncts to other analgesics after surgery (1). Administration of local anaesthetics (LA) into the surgical wound may modulate pain at the peripheral level and has been widely used in minor surgical procedures (4–10) as well as attracting renewed interest in major surgery. However, despite the widespread use, its scientific documentation from controlled studies has been relatively sparse and not hitherto reviewed.

This review describes the effects of LA administered at the wound site on nociception and the inflammatory response. Furthermore, the effects of LA on pain and morbidity after abdominal and gynaecological surgery in adult patients are reviewed, based upon controlled clinical studies. It was not intended to include paediatric procedures, since postoperative paediatric pain represents separate problems of acute pain management.

NOCICEPTION, INFLAMMATION AND LOCAL ANAESTHETICS

Pain due to tissue injury is initiated by activation of peripheral C- and Aδ-afferent nerve terminals. Antidromic impulses in axons promote the release of substance P (sP) from nerve endings, and in combination with other algogenic substances (e.g. prostaglandins, leukotrienes, bradykinin, serotonin and histamine), sP promotes inflammation and sensitization of nociceptors, resulting in hyperalgesia (2, 11, 12). The afferent nociceptive barrage may induce hyperexcitability of central neurones (13) and elicit spinal cord reflexes that increase the activity of postganglionic sympathetic efferents which in turn may amplify inflammation (11). Thus, both the somatic and sympathetic nervous systems may play major roles, not only in afferent nociceptive transmission but also as mediators of inflammation and hyperalgesia (11). Furthermore, the wound may play an important role in releasing various factors mediating or amplifying the systemic response to surgery although the exact nature and relative role of these components are still unknown (14, 15).

Infiltration with LA inhibits the transmission of nervous signals from damaged tissue by blocking voltage dependent sodium channels within the nerves and displacing calcium ions from phospholipids of the nervous membrane. Furthermore, LA may reduce neurogenic inflammation by blockade of the axon reflex (16) and sympathetic efferents. In addition, *in vitro* studies have demonstrated LA to have numerous effects on nonneuronal cellular activities involved in the inflammatory response, including inhibition of granulocyte and lymphocyte function (17–21), fibroblast growth and collagen synthesis (22, 23), platelet aggregation (24), and production or release of phospholipase A_2, superoxide and histamine (25–28). A recent study has demonstrated administration of LA in surgical wounds to reduce leukocyte migration and metabolic activation in the wound area (29). Furthermore, LA has been demonstrated to inhibit experimental peritonitis (30). Finally, LA have been demonstrated to have antimicrobial activity (31). However, the clinical implications of these findings for pain, inflammation and wound healing in surgical patients have yet to be clarified (32–34).

CLINICAL STUDIES

In order to evaluate existing data, they are discussed according to their design, i.e. an optimal design with

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placebo controlled studies, and non-placebo controlled randomized studies.

Placebo-controlled effects on postoperative pain and opioid requirements

The effect of administration of LA into the wound on postoperative pain and/or requirements of additional analgesics has been investigated in 13 randomized, double-blind, placebo-controlled studies with different surgical procedures (Table 1). In three of these studies, however, pain was not assessed (35–37) and in no study except one (38) was it specified whether pain was assessed at rest or during ambulation, which is important to give a full picture of an analgesic method (39).

In two of the 13 studies (40, 41), a clinically significant reduction in additional opioid requirements (from 18 to 9 doses of meperidine 0.2 mg · kg · 24 h^{-1} (40) and from 407 mg to 256 mg (mean values) meperidine · 24 h^{-1} (41)) together with a significant decrease in pain intensity was demonstrated. In one study (42), a clinically significant decrease in pain intensity was demonstrated, and in another study (36), a clinically significant decrease in opioid requirement (from 10.9 to 6.6 "narcotic doses" · 72 h^{-1}) was demonstrated while pain was not assessed. In another two studies (38, 43) a statistically significant decrease in opioid requirements was demonstrated (from 84 mg to 61 mg (mean values) methadone · 78 h^{-1} (43), and from 64 mg to 20 mg (mean values) pethidine · 24 h^{-1} (38)). However, such small reductions in opioid requirements may be of less clinical relevance. In the study by Levack et al. (43), pain decreased after wound perfusion both with bupivacaine *and* with placebo (saline), and pain was not different between the two groups before and after wound perfusion. Furthermore, a higher baseline pain score with bupivacaine suggested, that twice daily perfusion "was inadequate and perhaps even a disadvantage", although the latter was not documented by their results (43). In the herni-

Table 1

Effect of incisional LA on postoperative pain and requirements of additional analgesics. Randomized, blinded, placebo-controlled studies. ↓↓ = statistically and clinically significant effects. ↓ = statistically significant effects. → = not different from placebo.

Ref.	Local anaesthetic/ concentration	Method of administration	Volume (ml)	Type of surgery	Effect on: pain intensity	Effect on: opioid requirements
Chester J F et al. (40)	bupiv. 0.5%/0.25%	bolus/cont. infusion subfascial	10 · 4 h^{-1} in 24 h	cholecystectomy	↓	↓↓
Partridge B L et al. (41)	bupiv 0.25%	one infiltr. muscle, fascia, subc	30	upper/lower abdominal	↓	↓↓
Patel J M et al. (36)	bupiv. 0.25%	one infiltr. peritoneum, muscle, subc.	50	cholecystectomy	?	↓↓
Bays R A et al. (42)	bupiv. 0.5%	one application wound irrigation spermatic cord, fascial, subc.	15 (?)	inguinal hernia	↓↓	↓
Sinclair R et al. (38)	lidocaine spray, 100 mg · ml^{-1}	one application subcutaneous	2	inguinal hernia	↓	↓
Levack I D et al. (43)	bupiv. 0.5%	repeated injections subfascial	10 · 12 h^{-1} in 72 h	cholecyst./splenectomy	→	↓
Trotter T N et al. (47)	bupiv. 0.5%	one infiltr. subcutaneous	20	caesarean section	→	→
Thomas D F M et al. (35)	bupiv. 0.5%	repeated injections subfascial	10 · 4 h^{-1} in 48 h	cholecystectomy	?	→
Gibbs P et al. (44)	bupiv. 0.5%	cont. infusion subfascial	2 · 5 · 1 h^{-1}	cholecystectomy	→	→
Holst P et al. (45)	lidocaine spray 100 mg · ml^{-1}	one application subcutaneous	2	gynaecological laparotomy	→	→
Pfeiffer U et al. (46)	bupiv. 0.25%	repeated injections subcutaneous or rectus sheath	40 · 4 h^{-1} in 48 h	abdominal aortic surgery	→	→
Adams W J et al. (48)	bupiv. 0.25%	one infiltr. or topical application peritoneal/fascial/subcutaneous	40	cholecystectomy	→	→
van Raay J J A M et al. (37)	bupiv. 0.25%	one infiltr., peritoneum, fascia, subc.	50	cholecystectomy	?	→

...tomy study by Sinclair et al. using lidocaine spray 200 mg (38), pain was only modestly decreased during the first 24 h after surgery. No difference in pain during mobilization could be demonstrated between lidocaine and placebo treated patients although pain on unspecified palpation of the wound was significantly decreased in patients treated with lidocaine spray (38).

In seven studies (35, 37, 44–48, Table 1), no effect of wound infiltration with bupivacaine (35, 37, 44, 46–48) or lidocaine spray (45) compared to placebo was demonstrated. In the study by Thomas et al. (35) (Table 1), patients perfused with bupivacaine or saline received significantly less papaveretum than unperfused patients. This finding may indicate a therapeutic effect of perfusion of surgical wounds with saline since a similar effect was observed in another study (43). It may, however, also be due to a placebo effect (35, 43). In the study by Trotter et al. (47), pain was similar to bupivacaine and placebo treated patients although a small statistically significant difference in weight-adjusted morphine consumption was demonstrated (47).

In summary, in six of 13 randomized, blinded, controlled studies of incisional LA vs placebo (36, 38, 40–43), a statistically significant decrease in pain and/or opioid requirements was demonstrated, but in two studies (38, 43) the demonstrated significant small decrease in pain and/or need for additional analgesics may not seem of clinical importance. In the remaining seven studies (35, 37, 44–48), no effect of LA on pain or opioid requirements was demonstrated. Taken together, the available data from moderate to major size operations have demonstrated incisional local anaesthetics to have only a rather small effect on pain and/or opioid requirements, and probably without important clinical relevance.

Effects on postoperative pain and opioid requirements in non-placebo-controlled randomized studies

In addition to the studies in Table 1, four non-placebo-controlled and/or not-blinded/randomized studies have been published (49–52, Table 2). In one study (50), the number of doses of papaveretum 15 mg im were compared to the number of injections of bupivacaine 5 mg·ml^{-1}, 10 ml through a catheter placed subcutaneously following herniorrhaphy; patients in the opioid group required an average of 1.7 doses of papaveretum while patients in the local anaesthetic group required an average of 1.3 doses of bupivacaine. However, pain was *not* assessed (50). In another study (49), no effect of bupivacaine 5 mg·ml^{-1}, 10 ml injected deep to the external inguinal ring after herniorrhaphy was demonstrated on pain or opioid-requirements compared to a control group. In the study by Egan et al. (51) in patients receiving infiltration into the fascia with bupivacaine 2.5 mg·ml^{-1}, 2 ml·cm^{-1} incision after elective laparotomy (51), no difference in requirements of additional analgesics was demonstrated and pain was *not* assessed. However, time to first analgesic was significantly increased, although only from 1.3 h to 2.2 h (51). Finally, in the study by Tverskoy et al. (52), time to the first request for analgesic, and pain scores during rest and mobilisation 24 and 48 h postoperatively were significantly reduced in patients receiving subcutaneous and intramuscular infiltration of the abdominal wall with bupivacaine 2.5 mg·ml^{-1}, 40 ml before herniorrhaphy, compared to a control group receiving the same amount of systemic analgesics only. Summarizing, it is impossible to draw a clinically useful conclusion based on these few non-placebo controlled studies since pain was not assessed (50, 51), or a rather small amount of LA was given (50, 51) or administered at a suboptimal place (49). Thus, only the well-performed study by Tverskoy et al. (52) suggests incisional LA to be of clinical importance, but obviously needs to be confirmed by others.

Influence of dosage, site and time of injection

In 11 of 13 placebo controlled studies (Table 1), bupivacaine 0.5% or 0.25% was used for infiltration and/or continuous infusion. In two studies lidocaine was used as spray (Table 1, 38, 45). No dose-response studies have been published.

In two studies with clinically significant decreases in pain and/or opioid requirements (36, 41) peritoneum, fascia, muscle and subcutaneous tissue was infiltrated with intermediate – to high-dose/high-volume bupivacaine regimens (Table 1). In the study by Chester et al. (40), with significant effects on both pain and need for additional analgesics, a catheter was placed between peritoneum and the rectus sheath, and 10 ml bupivacaine 0.5% was injected followed by continuous infusion of bupivacaine 0.5%, 4 ml·h^{-1}; the patients thus received 530 mg of bupivacaine during a 24 h period (Table 1). In one study of herniotomy patients, with significant effects on pain (42), approximately 15 ml of bupivacaine 0.5% was bathed along the spermatic cord, fascia and subcutaneously (42).

In the two studies with minor clinical effects (38, 43), only one layer was infiltrated (43) or sprayed (38), and in addition rather small doses/volumes of LA were used (38, 43, Table 1).

Of seven studies without clinical effects, small or moderate doses were infiltrated or sprayed to one layer in two studies (44, 45, Table 1). In the large dose study by Thomas et al. (35), a catheter was placed between peritoneum and the rectus sheath, and 10 ml

Table 2

Effect of incisional LA on postoperative pain and requirements of additional analgesics. Randomized, non-placebo controlled studies. ↓↓ = statistically and clinically significant effects. ↓ = statistically significant effects. → = no effect.

Ref.	Local anaesthetic/ concentration	Method of administration	Volume (ml)	Type of surgery	Effect on: pain intensity	Effect on: opioid requirements
Hashemi K et al. (50)	bupiv. 0.5%	repeated injections subcutaneous	10	inguinal hernia	?	↓↓
Cameron A E P et al. (49)	bupiv. 0.5%	repeated injections external inguinal ring	10	inguinal hernia	→	→
Egan T M et al. (51)	bupiv. 0.25%	one infiltr. intra-fascial	2 ml/cm incision	upper/lower abdominal	?	→
Tverskoy M et al. (52)	bupiv. 0.25%	one infiltr. subcutaneous/intra-muscular *pre-operatively*	40	inguinal hernia	↓↓	-

bupivacaine 0.5% was injected followed by repeated injections of bupivacaine 0.5%, 10 ml·4 h^{-1} for 60 hours. In another large dose study (46), bupivacaine 0.25%, 40 ml was injected every 4 h for a total of 48 h to one layer (subcutaneously or submuscularly) but without differences between patients treated with subcutaneously or submuscularly administered local anaesthetic (46).

Finally, three studies using an intermediate one-dose regimen with subcutaneous tissue infiltration (45) or infiltration of peritoneum, fascia and subcutaneous tissue (37, 48) did not show any advantageous effect of LA. Summarizing, it is not possible to draw relevant conclusions about dose-response relationship from these limited data. Neither has the optimal site for infiltration been systematically investigated. A continuous infusion may be more effective provided large doses are used (40). It is not possible to draw conclusions on differential potency of incisional LA in different surgical procedures since very different dose- and infiltration regimens have been employed.

Effects on postoperative morbidity

The effects of incisional LA on pulmonary morbidity and various pulmonary morbidity parameters have been investigated in seven placebo-controlled studies (35–37, 41, 43, 44, 46). Clinically significant advantages have been demonstrated in one study only (36), where high-dose/high-volume infiltration of peritoneum, muscle and subcutaneous tissues after cholecystectomy significantly reduced the incidence of atelectasis compared to control patients (3/17 vs 12/23). Arterial Po_2 and pulmonary function tests (functional vital capacity (FVC) and forced expiratory volume (FEV_1)) were also improved in patients receiving bupivacaine compared to saline (36). No effects on Pao_2, peak flow, FVC, FEV or chest infections by clinical evaluation (46), FVC or FEV_1 (37), vital capacity (VC) (35), Pao_2, peak-flow, or chest infections (44), or FVC (43) were demonstrated in five placebo-controlled studies (35, 37, 43, 44, 46), while Pao_2 was improved in bupivacaine treated patients compared to controls in one study (41). In the randomized, but not placebo-controlled moderate-dose study of 415 patients undergoing elective upper or lower abdominal surgery by Egan et al. (51), no effect was demonstrated on the incidence of postoperative atelectasis, pulmonary function tests or clinical signs of pulmonary infection (51). Positive effects on postoperative mobilization or re convalescence have not been mentioned in any study investigating the specific effect of infiltration of the surgical wound with local anaesthetic. However, in one study, incisional LA led to a 1 h earlier discharge from the postanaesthetic recovery unit (41).

In conclusion, infiltration of the surgical wound with local anaesthetics has not been demonstrated to have clinically important effects on postoperative morbidity.

Effects on the injury response to surgery

Afferent neural stimuli have been shown to be of major importance in mediating the injury response (14) and the wound may additionally play a major role in releasing various humoral factors mediating or amplifying this response (15). Modification of the stress response to surgery has been the goal of several investigations in recent years in the hope that attenuation of the increased demands on organ function may improve morbidity (14). Since this response is initiated at the start of surgery, preoperative blockade may reduce not only postoperative pain (vide infra) but also the stress response.

The effect of combined wound infiltration and peripheral neural blockade with LA on the injury response has been investigated in one study in inguinal

herniotomy (53). Preoperative high-dose infiltration of subcutaneous and muscular tissue plus ilioinguinal nerve blockade with bupivacaine 0.25%, 50–60 ml, followed by continuous infusion of the wound with bupivacaine 0.5%, 5 ml h^{-1} via an inwelling catheter placed at the superficial inguinal ring, attenuated the hyperthermic response but not leukocytosis and acute phase protein changes. The neural blockade was effective as judged by lack of increase in plasma cortisol and plasma glucose. Additional cooling of the wound, to enhance the local anaesthetic effect of wound perfusion with bupivacaine, did not modify the injury response (53). In one study postoperative incisional LA with lidocaine spray blocked the β-endorphin response to herniotomy (38), a finding which is difficult to explain since the stress response is initiated already after skin incision.

Systemic and local adverse effects

Signs of systemic toxicity have not been observed in any study in Tables 1 or 2. Plasma concentrations of LA have been investigated in one study using spray (38) and were found to be well below toxic levels (38). In a study by Martin & Neill (54), venous blood vessels after bupivacaine 0.5%, 40 ml with or without adrenaline (1:200 000) were studied following local infiltration of the lower abdominal wall in 16 patients undergoing laparoscopic sterilization. Mean peak plasma venous concentration following 0.5% plain bupivacaine was 2.23 ± 0.24 μg · ml^{-1} and following 0.5% bupivacaine with adrenaline 0.98 ± 0.10 μg · ml^{-1}. No signs of systemic toxicity were observed in any patient (54).

No untowards effects, evident from clinical examination, have been observed on wound healing in any study published. However, in one study with repeated injections through an inwelling catheter (49), organisms were cultured from 6 of 48 catheters, but infection of the wounds were not observed. In none of the published studies has a significant increase in wound infections been reported. In this context it is interesting that the LA themselves have been reported to have antimicrobial effects (31).

Wound infiltration with LA as preemptive analgesia

Pre-injury treatment with an analgesic interfering with initiation of pain in the periphery should minimize the activation and sensitization of peripheral nociceptors, thereby minimizing the noxious input into the central nervous system and attenuate the inflammatory response to surgical trauma. Furthermore, hyperexcitability of dorsal horn neurones may be reduced by such preemptive analgesia (13) and it has been suggested that *pre*operative administration of analgesics may be more effective than treatment initiated *post*operatively (55). In all 13 studies in Table 1, LA was administered postoperatively. In one recent study, preemptive spinal or incisional neural blockade before inguinal herniorrhaphy reduced late postoperative pain and wound tenderness compared with patients operated in general anaesthesia only (52). Another study has demonstrated increased time to first analgesic when incisional lidocaine was administered preoperatively compared to after surgery (56). However, preoperative infiltration of subcutaneous and muscular tissue plus ilioinguinal and iliohypogastric nerve blockade (inguinal field block) with lidocaine did not improve the quality or duration of analgesia and had no effect on the need for additional analgesic or late postoperative pain compared to an identical postoperative infiltration in inguinal herniorrhaphy (57). In another study, preoperative inguinal field block did not improve analgesia compared to postoperative instillation of the surgical wound with bupivacaine after herniotomy (58). Therefore, there is a major need for further studies of *pre*-versus *post*injury treatment with incisional LA before clinical recommendations can be laid down (59).

DISCUSSION

Topical administration of LA (infiltration or spray) in the surgical wound may have extended effects on hyperalgesia and postoperative pain due to interference with trauma-induced changes in the peripheral and central nervous system (52), but results from placebo-controlled trials may seem disappointing (Table 1). Infiltration with large volumes of LA, however, has provided substantial effects in some studies (36, 40, 41, 52). It is impossible from the available data to conclude that incisional LA may exert more analgesic power in small or moderate scale surgery versus major surgery. It is noteworthy, that only a very few placebo-controlled, blinded studies have been published, especially in surgical procedures such as herniorrhaphy and other "minor" abdominal procedures.

The inherent relatively short duration of action of the available LA's is a major problem, and irrigation of all parts of the wound may seem technically difficult to achieve with continuous infusion. Furthermore, most patients may require additional nerve blocks, opioids or other regimens. Thus, the combination of iliohypogastric and ilioinguinal nerve block with infiltration of the operative field is effective for inguinal surgery and may enhance ambulation and the return of normal daily activities compared to general anaesthesia (60). However, the effect on postoperative pain or morbidity of incisional LA combined with other

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analgesic regimens have not been studied in other types of surgery. Thus, there is a severe need for systematical investigations to evaluate the optimal method and time for infiltration, optimal dosage/volume, infiltration with LA as part of a multimodal pain treatment regimen, and to development of more effective methods for continuous irrigation. Furthermore, there is a need to develop new LA's with an extended duration of action or new formulations of the present available LA's to extend their duration of action. Until now, however, controlled trials investigating the ability of dextran to prolong the action of different LA's have been disappointing (61, 62). Incorporation of anaesthetic agents in lecithin-coated microdroplets is under investigation (63, 64), and may be of value for prolonged postoperative analgesia if local anaesthetics could be used in such a preparation. The potential prolongation of incisional LA with slow absorbable suspensions or liposomal preparations remains to be elucidated (65). Ropivacaine, a new long-acting aminoamide LA, has, in animal studies (66, 67) and in clinical studies (68), been demonstrated to possess a long duration of action and, furthermore, ropivacaine may decrease cutaneous blood flow in contrast to bupivacaine (66–69), although this has been disputed by others (70). However, no clinical data are available on incisional ropivacaine. Nevertheless, ropivacaine may offer an advantage in terms of cardiovascular toxicity (71–73) which may be especially relevant for infiltration anaesthesia, where rather large doses may be necessary.

Recently it has been recognized that opioid antinociception can be achieved by activation of peripheral opioid receptors (74) and that peripheral application of opioids may have clinical effects on postoperative pain (75) since intra-articular morphine has been demonstrated to have prolonged analgesic effects after knee arthroscopy (75). Such findings, together with results showing analgesic effects as well as modifying effects on the injury response of periperal application of NSAID preparation in superficial injury (76) may open up a new era of acute pain treatment. Thus, peripheral balanced analgesia with LA's, opioids, NSAID's or other agents administered at the site of injury, may be an important future alternative in the management of pain, similar to multimodal pain treatment ("balanced analgesia") at the spinal cord level with epidural analgesics (77).

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BUPIVACAINE INFUSION FOR ILIAC CREST DONOR SITES

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Pain is common after a bone graft has been taken from the iliac crest (Kurz, Garfin and Booth 1989). Local wound infiltration with bupivacaine at closure is effective, but relief lasts for only four hours (Todd and Reed 1991). We report a method of infusing bupivacaine which gives effective and lasting analgesia.

Patients and methods. Patients requiring iliac crest grafts were randomly selected to receive either bupivacaine infiltration at wound closure or bupivacaine infusion postoperatively.

For the infusion group, a fine-bore catheter was tunnelled into the wound between muscle and fat and used to infiltrate 0.5% bupivacaine solution at a rate of 5 ml/hour for 48 hours by a syringe driver. A drain was also used; drain and catheter were removed after two days.

For the infiltration group 10 ml of 0.5% bupivacaine solution was injected into the soft tissues by needle and syringe immediately before skin closure. A drain was used.

At 24 hours postoperatively, patients graded their pain on a visual analogue scale (Banos et al 1989; Campbell and Lewis 1990), taking zero as no pain and 10 as worst imaginable pain.

There were nine patients in the infusion group and seven in the infiltration group. The results were analysed by Student's *t*-test.

Results. All patients could distinguish iliac crest pain from that of other operation sites. The average pain score in the infusion group was 2.2 while that in the control group was 5.4 ($p < 0.01$).

Discussion. We have confirmed that infusion is a more effective method of pain relief than single infiltration. The technique is simple, but we recommend that the catheter is placed subcutaneously to reduce intraosseous absorption and the risk of toxicity (Gilman et al 1990).

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Postoperative Patient Controlled Regional Analgesia at Home

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Introduction

Many day surgery patients have moderate to severe pain at home in spite of analgesic medication. The problem is particularly distressing in patients undergoing procedures such as arthroscopies, skeletal surgery, breast augmentation and inguinal hernia surgery. Administration of local anaesthetic in the surgical wound is effective and safe but the analgesia lasts only a few hours.

A new technique is described which allows the patient to self-administer local anaesthetic solution in the home environment.

Methods

One hundred and forty nine patients undergoing a variety of surgical procedures were included in this study (Table).

Multihole, thin (22 G) epidural catheters were placed in different areas and tunnelled 4-5 cm subcutaneously by surgeons, brachial plexus catheters were placed by anaesthesiologists. These catheters were connected to a lightweight, disposable, elastometric (balloon) pump containing 50-100 ml bupivacaine (Home pump,, Block Medical, Carlsbad, CA, USA) (Fig. 1).

The concentration and volume of local anaesthetic depended on catheter site and type of surgery. A simple procedure allowed patients to self-administer a prescribed dose of local anaesthetic (Fig.2).

Oral and written instructions included information about pump function, good hygiene around catheter site and the importance of closing the clamp after the prescribed time to avoid overdosage (Fig. 2). Patients were informed about symptoms of local anaesthetic toxicity, they also had 24-h access to medical help. When analgesia was not required any further, the patients removed the catheter and discarded the pump.

Follow-up consisted of evaluation of pain relief at home, pump function, use of rescue analgesic medication and overall satisfaction/dissatisfaction with the technique. The technique was tested in in-patients under nurse supervision prior to use in patients' home environment.

Results

Pain relief was graded good to excellent by 132 (88.6 %), adequate by 9 (6.0%) and poor by 8 (5.4 %) of patients.

Six (5.4 %) patients did not use the pump because of good analgesia following the first dose given at end of surgery. The catheter was dislodged in 2 patients.

Onset of analgesia was experienced within 5 min, the duration of analgesia after each administration of local anaesthetic varied from 2-8 h.

A majority of patients required 2-4 administrations. Patient follow-up did not reveal any infection or any problems with the technique, patient satisfaction was very high.

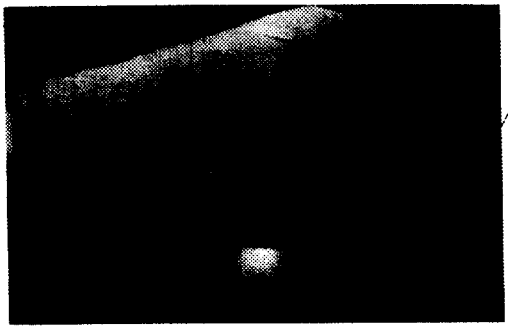

Fig. 1.

Diagnosis	No. of patients	Treatment at hospital	/ home	Site of catheter placement
Hand surgery				
Arthroplasty	20	8	12	Brachial plexus sheath
Arthrodesis	5	4	1	Surgical wound
Arthroscopy	18	2	16	Brachial plexus sheath
Soft tissue injury	32	7	25	Surgical wound or brachial plexus sheath
Tendon surgery	20	7	13	Surgical wound or brachial plexus sheath
Radius fracture	3	1	2	Surgical wound
Orthopedic surgery				
Arthroscopic subacromial decompression (ASD)	15	4	11	Subacromial
Shoulder arthroscopy (Bankart)	7	7	-	Intraarticular
Clavicle resection	2	-	2	Subacromial
Knee surgery	2	2	-	Surgical wound
Plastic surgery				
Breast augmentation	2	-	2	Surgical wound
Bone graft (iliac crest)	8	8	-	Near iliac crest (supraperiosteal)
Lymph node removal	2	2	-	Surgical wound
Maxillofacial/Oral surgery				
Mandibular reconstruction	7	7	-	Supraperiosteal
Multiple teeth extraction	3	1	2	Subalveolar
Arthroplasty (temporo-mandibular joint)	3	-	3	Supraperiosteal
Total	149	60	89	

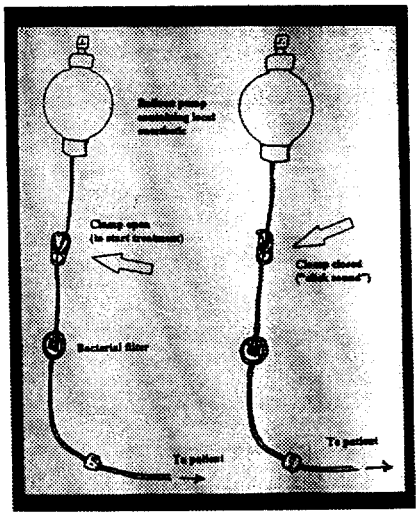

Fig. 2. When patient experiences pain the clamp is opened to start infusion.
After the prescribed time the patient closes the clamp ("click sound") to stop treatment.

Discussion

This preliminary study describes a new analgesic technique for day surgery patients with moderate to severe pain. The patient self-administers a prescribed dose of local anaesthetic delivered through a low-cost disposable pump via a catheter placed at a site appropriate for the type of surgery.

In the surgical procedures studied good to excellent analgesia was noted in nearly all patients. No complications were reported. Controlled trials are necessary to further evaluate the analgesia efficacy, risk of infection and indications for the use of this technique in the patients' home environment.Until such data are available, this technique should only be used if the patient has a 24-h access to medical help.

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Chemical Stability of Meropenem in Portable Infusion Pumps

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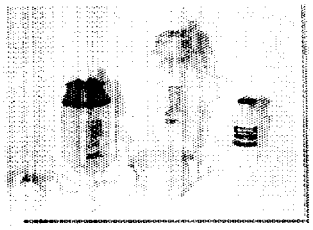
OBJECTIVES

The purpose of this study was to obtain documentation on the stability and compatibility of meropenem solutions prepared with sodium chloride 0.9% (NS) in two different portable infusion pumps, Intermate® and Home Pump® Eclipse.

STUDY DESIGN

Solutions containing 5, 10 and 20 mg/mL of meropenem were prepared by constituting 1.0 g vials of Meronem® with 20 ml of WFI and further diluting with NS. The solutions were then filled in Intermate®, 105 ml, and Home Pump® Eclipse, 100 ml, pumps which were stored at 4°C and 25°C. Analyses were carried out initially and after 6, 24 and 48 h storage at 25°C and after 24, 48, 72 and 96 h at 4°C.



ANALYTICAL METHOD

Samples were inspected visually and the pH was recorded. The content of meropenem was determined by a reversed phase HPLC-method. The stability indicating ability of the method is shown in Fig. 1. The method precision was ≤ 0.5%.

Column:	Hichrom HiRPB, 5µm particles, 3.2 x 150 mm
Mobile phase:	Acetonitrile : Methanol : Water : 0.1 M TBAH in methanol, (30 : 20 : 170 : 3). pH adjusted to 7.5 with 0.1 M H_3PO_4
Flow rate:	0.65 mL/min
Detection:	UV at 300 nm

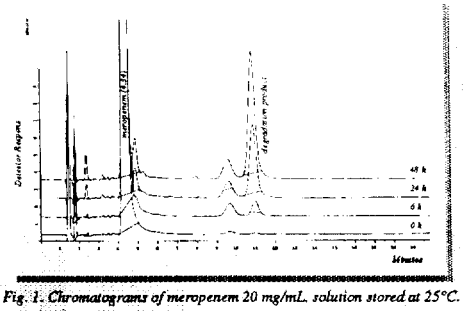


Fig. 1. Chromatograms of meropenem 20 mg/mL solution stored at 25°C.

RESULTS

The stability of meropenem in NS was found to be strongly dependent on both storage temperature and drug concentration. See Table 1 and Fig. 2.
Only minor changes in pH were noted, but the colour of the solutions changed gradually from almost colourless to strongly yellow depending on potency and storage temperature.
No significant difference in stability for solutions stored in the different reservoirs could be seen.

Table 1. Chemical stability

Conc.	$t_{90\%}^{4°C}$	$t_{90\%}^{25°C}$
5 mg/mL	>96 h	26 h
10 mg/mL	96 h	20 h
20 mg/mL	72 h	14 h

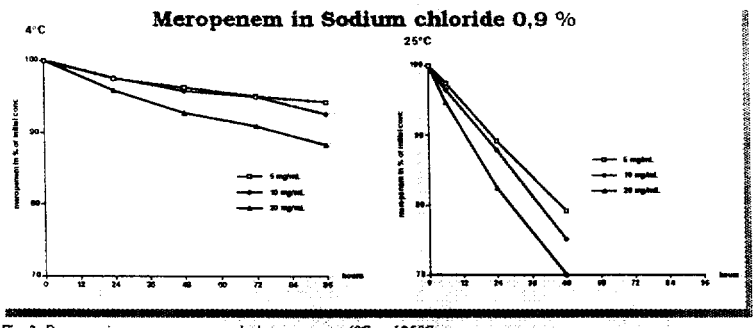


Fig. 2. Decrease in conc. meropenem during storage at 4°C and 25°C.

CONCLUSION

At the estimation of the utility time the warming-up period of 4 - 6 h required to achieve the nominal flow-rate of the pump devices must be considered. Estimated utility times, if a maximum of 10% degradation is accepted, are given in Table 2.
When doses of 2 g are needed the use of larger volume pumps that allows concentrations of ≤10 mg/mL are recommended to obtain a better stability. Administration time exceeding 1 hour is to be avoided for therapeutic reasons.

In conclusion, despite relatively short stability, meropenem can be stored and administrated in portable infusion pump systems. Especially for patients suffering from e.g. cystic fibrosis this offers the advantages of home i.v. antibiotic therapy.

Table 2. Utility time

Conc.	Refrig. (+ 4°C)	RT (+ 25°C)	Utility time
5 mg/mL	96 h	6 h	102 h
10 mg/mL	72 h	6 h	78 h
20 mg/mL	24 h	6 h	30 h

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Postoperative Patient-Controlled Local Anesthetic Administration at Home

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For most day-surgery patients, postoperative pain can be managed adequately at home with conventional oral analgesics, such as paracetamol, nonsteroidal antiinflammatory drugs (NSAIDs), and weak opioids (codeine, dextropropoxyphene). However, for moderate to severe pain, this treatment may be inadequate (1–4). Our recent study of 1030 patients undergoing a variety of day-surgical procedures (5) showed that approximately 30% of patients experienced moderate to severe pain at home. Severe pain was experienced by many patients who underwent the following surgeries: orthopedic (knee, shoulder, iliac bone graft, maxillofacial, halux valgus), breast augmentation, inguinal hernia, and varicose veins. We describe a technique using an elastometric balloon pump, which allows the patient to self-administer local anesthetic analgesia at home. This study was undertaken to evaluate the safety and applicability of the technique in a wide range of surgical procedures.

Methods

Ethics committee approval was obtained for this preliminary prospective study of 70 patients undergoing a variety of day-surgical procedures (Table 1). Informed consent was obtained from each patient at the time of preoperative evaluation. The technique involves the placement of a multihole, thin (22-gauge) epidural catheter (B. Braun, Melsungen, Germany) subcutaneously into the surgical wound, subacromially, intraarticularly, or in the axillary brachial plexus sheath (Table 1). The catheter was tunneled 4–5 cm subcutaneously by the surgeon and firmly secured on the skin by using sterile tape (Proxi-Strip®; Johnson & Johnson). Axillary brachial plexus catheters were placed and secured in position by anesthesiologists. The catheters were introduced 3–5 cm within the sheath and secured to the skin by using transparent dressing and tape.

These catheters were used for surgery and postoperative analgesia. They could be secured in less than 5 min. Using aseptic technique, the catheters were connected to a 50- or 100-mL elastometric (balloon) pump (Fig. 1) with the appropriate concentration and volume of local anesthetic drug (Home pump®; I-Flow Corporation, Lake Forest, CA). The balloon pump was filled with a volume of local anesthetic to provide 10 doses for postoperative pain management. The Home pump® is designed and approved to deliver intravenous antibiotics and cytostatic drugs and costs approximately $15–$20. Postoperatively, when the patient feels pain, the local anesthetic infusion is started by opening the clamp (Fig. 2a). The patient stops the infusion by closing the clamp after the prescribed time (usually 6 min) or earlier if pain relief is adequate (Fig. 2b). When the patient no longer requires analgesia, he or she removes the tape, pulls out the catheter, and discards the pump. In most cases, the patient self-administers the first dose in the postanesthesia care unit (PACU).

Bupivacaine 0.125% was used in brachial plexus catheters; in all other catheters, a 0.25% concentration was used. The 0.125% solution was used to reduce or avoid the risk of possible injury due to excessive motor block. The maximal volume of local anesthetic allowed for each administration was 2.5 mL for maxillofacial surgery, 5–10 mL for surgical wounds, and 10 mL for the remaining procedures. An appropriate pump (50 or 100 mL) filled with local anesthetic to provide 10 doses at home was given to the patient before discharge. The patient was instructed to avoid using the pump more than once every hour.

Before using the technique at home, it was evaluated in 35 inpatients. These patients were given instructions, which were later provided in similar form

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0003-2999/97/$5.00

Table 1. Use of Patient-Controlled Regional Analgesia After Various Surgical Operations

Diagnosis	No. of patients	Treatment at hospital / home		Site of catheter placement
Hand surgery				
Arthroplasty	8	7	1	Brachial plexus sheath
Arthrodesis	2	2	—	Surgical wound
Arthroscopy	6	2	4	Brachial plexus sheath
Soft tissue injury	13	5	8	Surgical wound (n = 7)
Tendon surgery	10	5	5	Plexus sheath (n = 6) Surgical wound (n = 6)
Radius fracture	2	1	1	Plexus sheath (n = 4) Surgical wound
Orthopedic surgery				
Arthroscopic subacromial decompression	14	4	10	Subacromial
Shoulder arthroscopy (Bankart)	3	—	3	Intraarticular
Knee surgery	1	1	—	Surgical wound
Plastic surgery				
Breast augmentation	2	—	2	Surgical wound
Bone graft (iliac crest)	4	4	—	Near iliac crest (supraperiosteal)
Lymph node removal	2	2	—	Surgical wound
Maxillofacial/oral surgery				
Mandibular reconstruction	1	1	—	Supraperiosteal
Multiple teeth extraction	1	1	—	Subalveolar
Arthroplasty (temporomandibular joint)	1	—	1	Supraperiosteal
Total	70	35	35	

In plexus catheters, 0.125% bupivacaine was administered; in all other catheters, the concentration was 0.25%. The volumes of bupivacaine were as follows: maxillofacial surgery 2.5 mL, wound infiltration 5–10 mL, shoulder and knee surgery 10 mL.

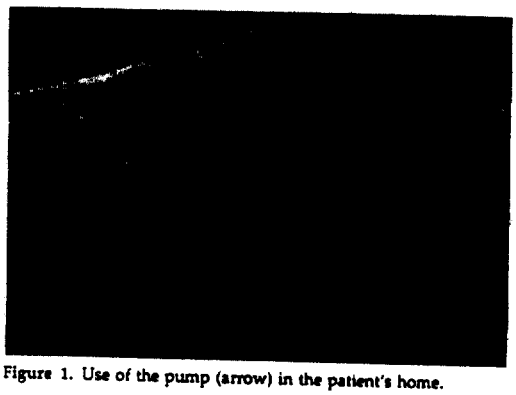


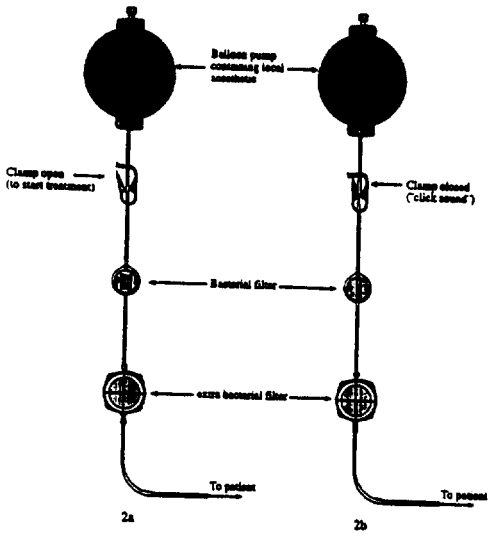
Figure 1. Use of the pump (arrow) in the patient's home.

to the home patients. The written instructions to the patients included information about: a) symptoms of local anesthetic overdosage; b) protection of the catheter and pump system during washing, showering, etc.; c) catheter removal before discarding the pump; and d) how to contact nurses and anesthesiologists.

Additionally, the patient was given a form on which to record the following: pain intensity on a verbal scale (severe, moderate, mild, none) after each treatment, the clock time of each administration, the total number of times a local anesthetic was self-administered, use of "rescue" analgesic tablets (NSAIDs, acetaminophen/codeine, or acetaminophen/dextropropoxyphene), technical problems with the pump, and overall satisfaction/dissatisfaction (excellent, adequate, poor) with analgesia. Onset of analgesia was assessed from first administration of local anesthetic in the PACU and from patient comments. The duration of analgesia was evaluated from the clock time at each administration. The patient was given a stamped, self-addressed envelope in which to return the completed questionnaire within 2–3 days after surgery. A nurse made a follow-up call the day after surgery and inquired about the patient's general condition, pump function, satisfaction/dissatisfaction with analgesia, and suggestions for improving technique.

Results

Seventy patients received analgesia by self-administration of local anesthetic solution on demand. All patients (100%) returned the completed questionnaire. The results are based on data from inpatients, PACU, and patient comments from the questionnaire. None of the patients had any problems using the pump. The onset of analgesia was usually within 5 min but was longer (up to 15 min) in patients with brachial plexus and subacromial catheters. The duration of analgesia after each administration of local



When patient experiences pain the clamp is opened (Fig. 2a) to start infusion. After the prescribed time the patient closes the clamp ("click sound") to stop treatment (Fig. 2b).

Figure 2. Self-administration of the local anesthetic solution by a patient. On opening the clamp (a), the solution starts running into the catheter. After the prescribed time (usually 6 min), the patient closes the clamp (confirmed by a clicking sound) to stop the infusion (b). The patient is encouraged to use a timer as a reminder to close the clamp.

anesthetic varied from 2 to 8 h. Most patients required two to four administrations.

Six patients did not use the pump at home because the first dose of local anesthetic in the hospital provided prolonged pain relief; these patients were not included in the data analysis. Pain relief was considered good to excellent by 57 (89%) patients, adequate by 4 (6%) patients, and poor by 3 (5%) patients. However, 4 patients complained that the total amount of medication was insufficient (all had received a 50-mL pump). Except for the above-mentioned 3 patients with poor analgesia and 4 patients who received an insufficient dose of local anesthetic, none required analgesic tablets. Follow-up calls confirmed that the technique was generally perceived as simple and effective. No technical problems were encountered. None of the patients reported any symptoms of local anesthetic toxicity. One patient commented that the act of removing the catheter was unpleasant. One patient with opioid dependency required unusually large doses (three doses of 20 mL 0.25% bupivacaine subacromially during a period of 1.5 h). Although this patient was asymptomatic, a bupivacaine level was drawn approximately 2 h after the first dose and was found to be 1.15 μmol/L, which is well below toxic levels.

Discussion

Effective management of pain may make the difference between surgery being performed on an inpatient or day-care basis. Although NSAIDs, paracetamol, and weak opioids, such as codeine and dextroproxyphene, are adequate for mild to moderate pain, these drugs may be ineffective in patients with moderate to severe pain. Local anesthetic infiltration in a wound or close to peripheral nerves is not common; in several studies, it has been demonstrated as a highly effective analgesic technique (6–10). Infiltration with local anesthetics modulates pain at the peripheral level by inhibiting the transmission of nociceptive impulses from the site of injury. The technique is generally considered to be simple, safe, and inexpensive. The main limitation to its widespread use is the need for repeated administration because of the short analgesic effect (usually two to six hours) of a single dose. Intermittent injections or continuous infusions through indwelling catheters in the wound area have been described for inpatients (6–10,11). Our preliminary data show that this technique can also be used at home. This study demonstrates the safety, efficacy, and applicability of the technique in a wide range of surgical procedures. Although nearly all patients had adequate to excellent pain relief, the efficacy of this technique was not compared with that of oral analgesics.

The major concern with this pump system is that the entire volume of local anesthetic will be delivered if the patient fails to close the clamp. To avoid this complication, the following steps were taken: a) oral and written information was given to the patient and the escort, b) the use of a timer was encouraged, c) the patient was informed that a clicking sound is heard when the clamp is closed, and d) the patient was instructed to close the clamp and contact an anesthesiologist if there was numbness of the tongue or tinnitus. The "worst-case scenario" is that all 50 mL of 0.125% or 0.25% bupivacaine is delivered (100 mL is used only for shoulder surgery), and although technically possible, this should not lead to any serious problems because the local anesthetic is delivered to peripheral tissue, the drug is delivered over a period of 1 h, and the total dose of bupivacaine is large but not excessive. The doses we used are far smaller than some reported in the literature. Single infiltration by 50 mL 0.25% bupivacaine after cholecystectomy (12,13) and repeated administration of 10 mL 0.25% bupivacaine every 4 hours for 48 hours (14, 15) have been reported. Doses up to 40 mL 0.25% bupivacaine every 4 hours for 48 hours have been administered subcutaneously to treat pain after abdominal aortic surgery, and no signs of systemic toxicity were observed in any of these studies (16). However, it may

not be valid to compare the intermittent administration of large doses of local anesthetics and accidental administration of 50–100 mL of 0.125% or 0.25% bupivacaine within one hour.

Other concerns may be the risk of delayed wound healing and infection. The latter may be particularly important for intraarticular technique. The literature does not support these concerns. Indeed, local anesthetic drugs have bacteriostatic and antimicrobial effects (17–19). The surgeon tunnels the catheter under the skin so that it exits 3–5 cm from the wound. This procedure reduces the risk of infection and catheter dislodgment. The closed pump system described herein avoids repeated injections and handling of the catheter, thereby further reducing the risk of infection. A bacterial filter is included in the pump system (Fig. 2), and an additional bacterial filter was used in this study. Nevertheless, the risk of infection at home needs to be studied in more detail.

Although there were no complications in any of our 70 patients, we emphasize that our results are preliminary. Controlled trials are necessary to compare this technique with traditional methods and to evaluate the optimal concentration and volume of local anesthetic. The role of opioids and nonopioids, such as NSAIDs and clonidine, as adjuvants to local anesthetic drugs also needs to be studied.

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Pleural Anesthetics Given Through an Epidural Catheter Secured Inside a Chest Tube

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Pain management after thoracic surgical procedures is a difficult clinical problem. A variety of pain management methods are used with variable efficacy. This paper presents an effective method of pleural anesthetic administration using a pleural catheter inserted through a chest tube.

(Ann Thorac Surg 1991;51:138–9)

Analgesia after thoracotomy, tube thoracostomy, or thoracic trauma may pose a difficult problem for the surgeon and the patient. A variety of analgesic methods are currently available including narcotic agents, patient-controlled analgesics, intercostal nerve blocks, and pleural anesthetic agents. Moderate- to long-acting local anesthetics (eg, bupivacaine) administered into the pleural space provide a safe and effective method of pain control in thoracic surgical patients [1, 2] as well as in abdominal surgical patients [3, 4]. This type of anesthetic administration may decrease narcotic requirements and, therefore, decrease narcotic side effects such as respiratory depression and paralytic ileus [5]. Pleural anesthetics do not require the multiple percutaneous injections with the risk of intravascular injection of anesthetic or of pneumothorax during the administration of intercostal nerve blocks. Pleural anesthetics can be administered either through an indwelling pleural catheter or through a chest tube. Pleural catheters maintain a closed sterile system preventing contamination and avoiding other mechanical problems associated with injections directly into chest tubes such as pneumothorax. Pleural catheters may be placed percutaneously during thoracotomy but can be difficult to position optimally. Likewise, placement during tube thoracostomy may be difficult owing to the small caliber and flexibility of the catheters. This paper describes a method of percutaneous placement of a pleural catheter through a chest tube, enabling safe, easy, and accurate catheter placement during thoracotomy or tube thoracostomy.

Technique

We use a standard epidural catheter insertion set and a standard chest tube. The epidural introducer needle is

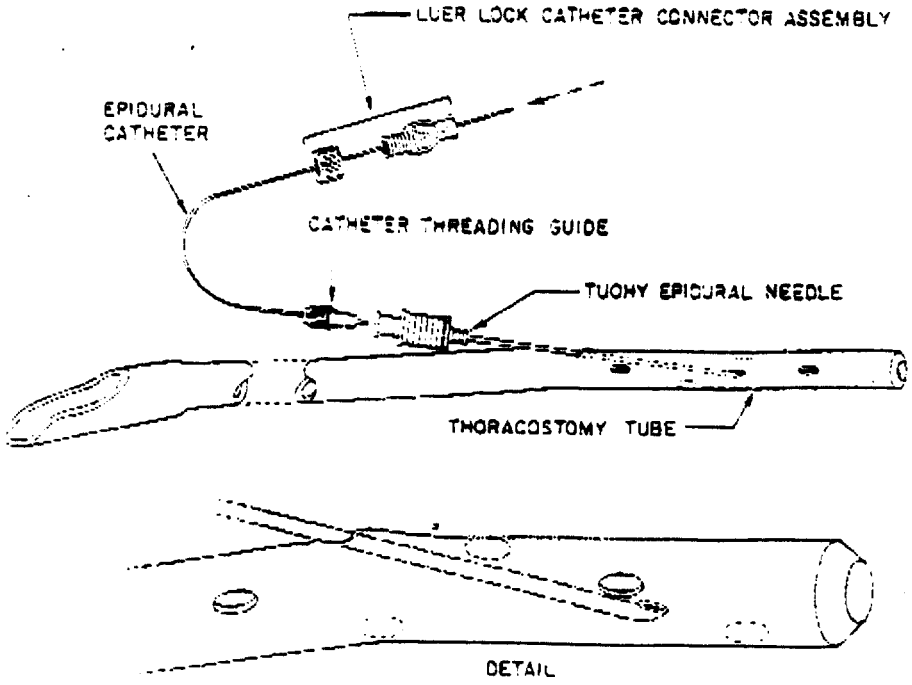

Fig 1. The catheter is advanced through the introducer needle, which is inserted through the side of the chest tube near the hole closest to the chest bottle. The tip of the catheter is positioned approximately 1 cm from the tip of the chest tube, then the introducer needle is removed. The Luer lock adaptor is then attached to the proximal end of the pleural catheter.

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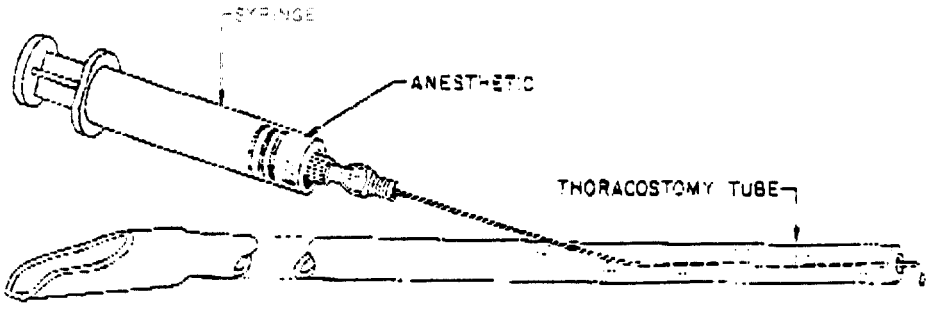

...during thoracotomy or percutaneously using standard tube thoracostomy techniques. The tip of the catheter is positioned posteriorly and at the apex. The catheter is firmly attached to the external portion of the chest tube with tape.

inserted through the side of the chest tube near the hole closest to the chest bottle. The epidural catheter is then inserted through the needle and advanced until its tip protrudes about 1 cm through the distal end of the chest tube (Fig 1). The combined assembly is then inserted percutaneously using standard tube thoracostomy techniques. If placed during an intrathoracic procedure, the catheter is inserted into the chest tube after the tube has been pulled through the chest wall. The entry site of the catheter into the chest tube should be positioned within the pleural space to prevent potential air leak. Ideally, the assembly should be positioned posteriorly within the pleural space.

After insertion, the pleural catheter can be secured to the chest tube with ½-inch tape but not tied with the chest tube stitch. The pleural catheter is then fitted with a Luer cap that will allow injections directly through the rubber diaphragm (Fig 2). Local anesthetics are administered through the pleural catheter as needed. We use preservative-free 0.25% bupivacaine with epinephrine at 0.3 mL/kg every 6 hours as needed for pain. However, continuous infusion of local anesthetic agents may also be used [1]. The maximum safe dose of 0.25% bupivacaine with epinephrine is up to 1 mL/kg of body weight every 6 hours.

Comment

Pleural administration of local anesthetics is an effective method of pain management in patients undergoing thoracic surgical procedures including percutaneous tube thoracostomy [1, 2]. Administration requires either an indwelling pleural catheter or a chest tube. The former provides a closed system with maintenance of sterility and avoidance of mechanical problems associated with repeated injections directly into the chest tube. Pleural catheters can be placed directly during thoracotomy. Blind percutaneous placement may be difficult owing to the flexibility and the small caliber of these catheters. In addition, blind percutaneous placement carries a small risk of pneumothorax or lung injury [4]. The combination of pleural catheter and chest tube facilitates percutaneous placement and enables the surgeon to use pleural anesthetics in any patient requiring a chest tube. This system ensures good positioning of the catheter posteriorly and at the apex of the pleural space. It also prevents kinking or coiling of the pleural catheter, which may be a problem even with catheters placed during open thoracotomy. A closed sterile system without air leak is maintained. The catheter can also be securely attached to the chest tube, which helps avoid inadvertent removal. In our experience, efficacy is excellent and redosing is easy with use of a Luer lock adapter. We have used this technique in more than 25 patients undergoing either thoracotomy or thoracostomy tube placement. Specific surgical procedures include posterolateral thoracotomy for pulmonary resections, tube thoracostomy for pneumothorax, and tube thoracostomy after transhiatal esophagectomy.

In our experience, there have been no complications attributable to the pleural catheter nor have there been any instances of cardiac or central nervous system problems caused by the anesthetics. We have observed that when this technique is used, the patients rarely require parenteral narcotics during the 4 to 6 hours after administration of the anesthetics.

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Appendix E

Summary of Safety and Effectiveness

I-FLOW
-FLOW
CORPORATION
Lake Forest, CA 92630
(800) 448-3569 (714) 206-2700
Fax (714) 206-2600

SUMMARY OF SAFETY AND EFFECTIVENESS

February 11, 1998

Trade Name: PainBuster

Common Name: Elastomeric Infusion Pump

Classification Name: Pump, Infusion, Elastomeric

All questions and/or comments concerning this document should be made to:

Robert J. Bard, Esq., R.A.C.
Vice President Regulatory and Legal Affairs

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Telephone: 714.206.2700
Fax: 714.206.2600

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1.0 GENERAL INFORMATION

1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to market an intraoperative site infusion kit, the PainBuster™ Infusion System, that utilizes legally marketed components for a new intended use.

1.2 Statement of Equivalence

1.2.1 The PainBuster Infusion System is a kit which includes components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation).

1.2.2 The PainBuster Infusion System is substantially equivalent in intended use to the Pain Control Infusion Pump (PCIP) (K896422) distributed by Sgarlato Laboratories, Inc.

1.2.2.1 The Sgarlato PCIP kit contains an infusion pump produced by Burron/B. Braun, B. Braun catheter and Jelco needle.

1.2.2.2 The catheter and needle included in the PainBuster kit are separately purchased pre-amendment or 510(k) devices similar to the devices in the Sgarlato PCIP kit.

1.2.2.2.1 An example of the catheter included in the PainBuster kit is the B. Braun Perifix® Epidural Catheter Set.

1.2.2.2.2 An example of the needle included in the PainBuster kit is the Jelco™ Catheter Introducer Needle.

1.2.2.2.3 The PainBuster pump is substantially equivalent to the Homepump C-Series (K944692) and Homepump Eclipse (K932740) marketed by I-Flow Corporation.

1.2.2.3 The PainBuster pump's design is nearly identical to the original Homepump C-Series, see section 2.1 below.

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of Device

2.1.1 The PainBuster Infusion System is a kit that is comprised of an elastomeric infusion pump, a catheter and a needle.

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2.1.2 The PainBuster pump is the Homepump C-Series with a new intended use. The pump design is identical to the original Homepump C-Series except as follows:

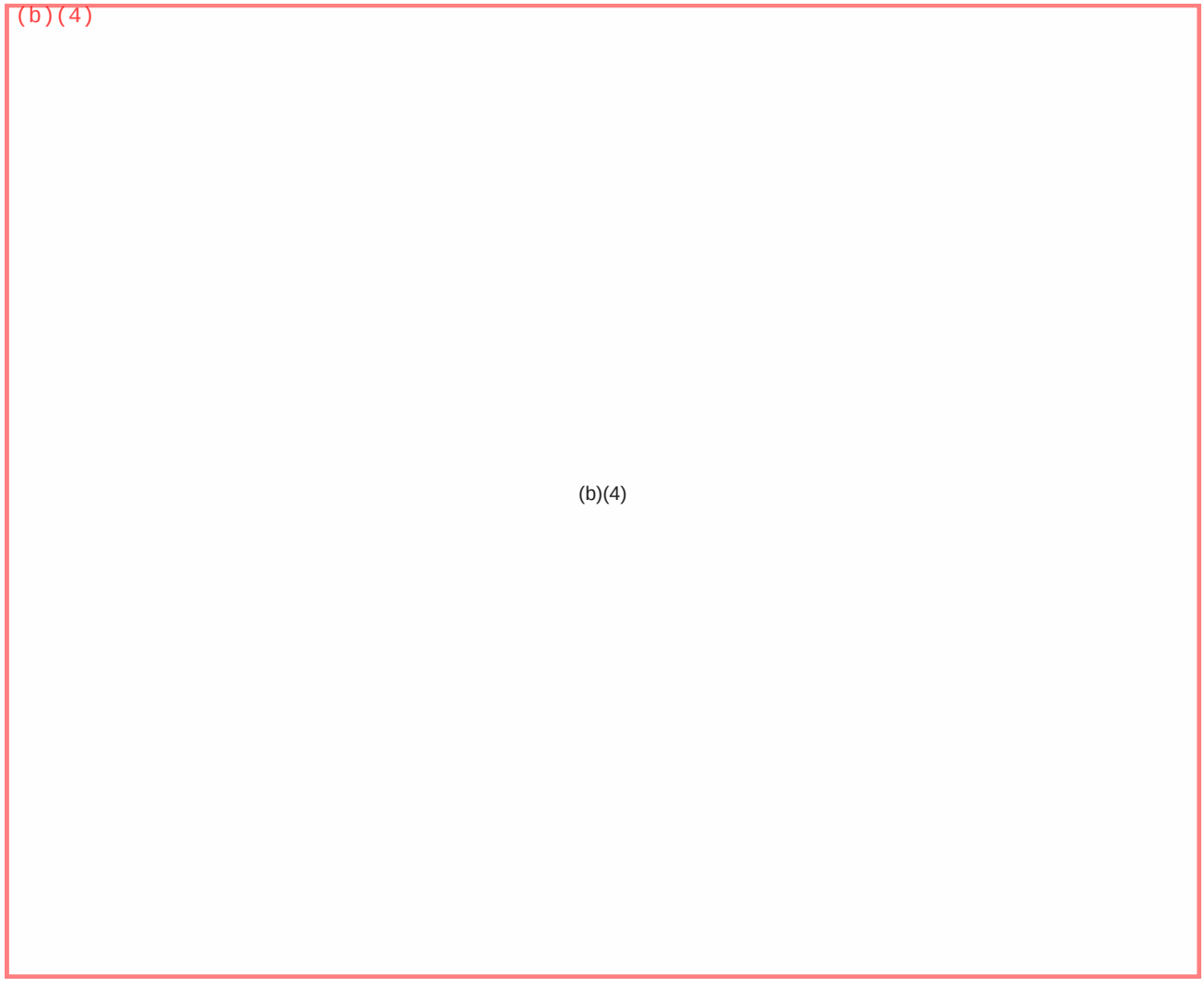
2.1.2.1 The PainBuster pump utilizes the same soft PVC shell that the Homepump Eclipse uses.

2.1.2.2 The two (2) outer natural latex bladders have been replaced by a single thicker natural latex bladder.

2.1.2.3 The PainBuster pump is intended to be used with a catheter that is included with the kit.

2.2 Product Configuration

(b)(4)



144

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

149